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CLINICAL INVESTIGATION PROGRAM REPORT

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ARMY MEDICAL CENTER

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Subject report identifies the research activities conducted by Dwight David Eisenhower Army Medical Center investigators through protocols approved by the Institutional Review Committee for registration with the Department of Clinical Investigation during Fiscal Year 1992, and other known publications and presentations by the Dwight David Eisenhower Army Medical Center professional staff. A detail sheet of each protocol giving the objective, technical approach, and progress is presented.

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CLINICAL INVESTIGATION

PROGRAM REPORT

1 October 1992

CONTROL SYMBOL: RCS MED-300 (R1)

Department of Clinical Investigation
Dwight David Eisenhower Army Medical Center
Fort Gordon, Georgia 30905-5650

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FOREWORD

The cover this year features a medieval chemist. He represents a transitional era in chemistry between the ancient and the modern. He also represents a unique position between a modern chemist and a physician or pharmacist. Much of the drive in ancient chemistry was related to the medical uses of natural products. Its basic philosophical premise was the four elements of nature (fire, air, water, and earth) and the four humors in health (blood, phlegm, yellow and black bile). This Pythagorean-Empedoclean theory was dominant for two millennia. The various *materia medica* prepared were based in part on empirical data and in part on theoretical issues (e.g. the degree of heat, cold, moistness, or dryness of the substance or the plant part's resemblance to a human organ). The ancients were aware of the anesthetic qualities of *Solanaceae* alkaloids mixed with opiates. The problem with their usage was the narrow therapeutic range and the variability inherent in the active principle in a natural product. They could never be sure that a given dose might cause death or lack efficacy.

The rise of Arabic medicine incorporated Greek medicine transmitted through Christian and Jewish physicians in conquered lands of Syria and Persia. Its acceptance led to a flowering in medical practice in the Islamic lands. The Crusades and travel to the Moorish Iberian peninsula allowed for this knowledge to spread into Europe. The terms of aldehydes, alcohol, and alkali were added to the language by their developments. They incorporated as drugs camphor, senna, mercury, aconite, and cloves. These were formulated in pleasant syrups, juleps, rose water, and orange water.

Unfortunately alchemy and astrology were exported along with the good. The alchemists premise was that all metals are in essence one and that some substance must exist to convert one to another (the philosopher's stone). The transformation of common metals into gold was of special pecuniary interest that stimulated much inquiry into science. Fortunately this search led to the discovery of methods to formulate a number of important chemicals: bismuth, antimony, zinc, phosphorus, mineral acids, mercury compounds, potassium nitrate, lead acetate, arsenious oxide. Basic chemical techniques of distillation, sublimation, filtration and crystallization were discovered along the way.

These basic chemical substances and their preparatory techniques were foundational for modern analytical and synthetic chemistry. The good was mixed in with the spurious and superstitious. This Arabic influence was responsible for the reintroduction of astrology into European medicine and science for a few centuries longer.

The pinnacle of Islamic science and medicine was Avicenna who wrote extensively on all aspects of both and also found time to write poetry (in Persian) that was later attributed to Omar Khayyam. His treatises on chemistry refuted the alchemists claim of transmutation of metals by asserting the fundamental differen-

ces of metals. His medical masterwork was the *Canon* which remained an authoritative work for five centuries. He also wrote a treatise *On the Uselessness of Astrology*. The great physician of the Western Caliphate, Avenzoar, also opposed astrology and mysticism in medicine.

From this at times unpromising origin, modern chemistry slowly emerged as a systematic science in the last two centuries. The relationship between chemistry and medicine remains a close one even as great advances continue in many other areas of chemistry. The need for highly specific chemical agents of great purity in medical use drives many developments in the broader science. Analytical techniques for vanishingly low levels of transient cell messengers under in vivo conditions continues to power both chemistry and medicine synergistically. The chemistry of the brain remains a frontier for both which is joined by the philosophers as well. Many of the great gains in the basic sciences flow from a focussed effort at certain practical problems.

Correspondingly, physicians need to be both scientist as well as philosopher and healer. Nothing sharpens the discernment of a physician as much as recognizing the limitations of his art through a well designed scientific study. He or she learns to appreciate the relationship between existing theory and the empirical knowledge of the particular through the design and analysis of a study. One must sort out the variables deemed important from the myriad which could be considered and be prepared for data which challenges dearly held prejudices.

Thus remains the challenge for educating new physicians in the finer points of medicine. The clinical investigation program keeps the mentors young in vision and the disciples wise in the application of their "physic."



Kent M. Plowman
COL, MC
C, Dept. Clin. Invest.

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UNIT SUMMARY - FISCAL YEAR 1992

A. Objective.

The Department of Clinical Investigation is responsible to the Deputy Commander for Clinical Services for providing the facilities and atmosphere of inquiry necessary to support and stimulate both basic and clinical medical investigation within DDEAMC.

B. Technical Approach.

All research, investigational, and training activities within the Department of Clinical Investigation are conducted under the guidance of AR 40-38, AR 40-7, AR 70-25, AR 70-18, and HSC Reg 40-23. Careful monitoring of all approved protocols is conducted in order to assure strict compliance with these applicable regulations.

C. Staffing.

Name	Rank	MOS	Title
Plowman, Kent M.	COL	61F00	Chief
Morse, Brent C.*	CPT	64A00	Veterinarian
Tobias, Steven **	CPT	64A00	Veterinarian
Sutherland, Donald E.	MAJ	68C9B	Biochemist
Turgeon, David K.#	MAJ	68A9B	Immunologist/Microbiologist
Craft, David##	MAJ	68A9B	Immunologist/Microbiologist
Williams, Linda E.	SSG	92B30	NCOIC, Med Lab NCO
Rodriguez-Morales, Janet	SSG	92B30R	Med Lab Sp
Marchand, Rita***	SPC	91T10	Veterinary Sp
Quilici, Kristine++	SGT	92B20	Med Lab Sp
Greer, Kim	SGT	92T20	Veterinary Sp
Horner, Jack A.	GM13	01301	Asst C, Res Histologist
McPherson, James C. III, PhD	GS13	01320	Biochemist
Runner, Royce R., MT, ASCP	GS11	00644	Medical Technologist
Challenger, Patricia, RN+	GS11	00610	Clinical Nurse
Best, Norma	GS9	00644	Medical Technologists
Chuang, Augustine H., Ph	GS9	00644	Medical Technologist (MRDC Grant)
Martinez, Rosina	GS7	00303	Protocol Coordinator
Searles, Rosa	GS6	00404	Biological Lab Technician
Reisenger, Rebecca	GS4	00312	Clerk-Steno
Zadinsky, James+++	GS7	01531	Stat Asst (Temporary)
Johnson, Glenda###	WG2	03502	Laborer (Temporary)

Officer: 4 authorized; 5 required; 4 assigned
 Enlisted: 5 authorized; 9 required; 4 assigned
 Civilian: 7 authorized; 13 required; 8 assigned

One third-party FACT physician assistant employee in Pulmonary Service.

*PCS Jul 92; **Assigned Aug 92; #PCS Aug 92; ##Assigned Jul 92; ###Temporary terminated Sep 92 ***ETS May 92; +Grant converted to permanent DCI Oct 91; ++Assigned Jan 92; +++Temporary terminated Apr 92

D. Funding.

Type	Fiscal Year 91	Fiscal Year 92
Civilian personnel to include benefits	246,070.00	310,959.00
Consumable supplies	75,900.00	118,789.00
Civilian contracts to include consultants	3,200.00	2,400.00
TDY	2,600.00	2,000.00
Publications	1,574.00	2,243.00
CEEP	34,578.00	2,499.00
MEDCASE	29,661.00	316,215.00
Military	534,424.00	497,794.00
Total	928,007.00	1,252,899.00

Grant Funding:

MRDC - "The Capsule of S. aureus: Bone Tropism, Adherence and Host
Immunity (Rat Model)."
FY 92: \$41,772.00

MRDC - "Non-ionic Surfactants in the Treatment of Third Degree Burns in
Rats."
FY 92: \$64,966.00

MRDC - "Metabolic Factors Influencing Recovery from Metabolic Acidosis."
FY 92: \$34,313.00

E. Progress.

Protocol Disposition FY 92

	<u>Completed</u>	<u>Terminated</u>	<u>Ongoing to FY 93</u>
FY 79	3		1
FY 84	1		
FY 85			1
FY 87	1		2
FY 88		1	2
FY 89	2	2	2
FY 90	3	4	5
FY 91	29	1	38
FY 92	11	6	60
	<hr/> 50	<hr/> 14	<hr/> 111

One study for FY 92 was withdrawn.

Number of resident and fellowship programs: 13
Number of programs using Clinical Investigation: 9
Number of residents and fellows on approved protocols: 60
Number of approved protocols held by this group: 62

Other training programs that use Clinical Investigation: Graduate Students,
Transitional Interns, Psychology Interns

Number of approved protocols held by this group: 5

Number of hospital staff members on approved protocols: 54
Number of approved protocols held by this group: 108

Drug evaluation/comparison studies: 74
Treatment evaluation/comparison studies: 23

RESEARCH AWARDS

Recipients of

The Tenth Annual DDEAMC Resident Research Award
were

Captain David E. Schenk, MC
Captain James Williford, MC
Captain Charles Perrotta Jr, MC
Psychiatry Residents

for their paper

"Fluoxetine vs Placebo in the Treatment of Late Luteal Phase Dysphoric Disorder"

The paper was based on Protocol 91-17 and was presented at the AMA National Conference in Washington, DC, in May 1992.

Recipient of

The Sixth Annual Dental Activity Resident Research Award
was

Major Betty G. Galvan, DC, Prosthodontic Resident

for her paper

"The Effect of Time Delay on Tensile Bond Strength of the Silicoated and Silane Treated Metal Surface," based on Protocol 91-61.

INSTITUTIONAL REVIEW COMMITTEE

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Chief, Department of Clinical Investigation, Chairman
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Chief, Department of Surgery
Chief, Pharmacy Service
Research Director, Dental Activity
Chief, Department of Ministry & Pastoral Care
Chief, Nursing Education & Staff Development
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Signal Center Representative, Ft Gordon, Georgia
Research Director, Department of Family Practice
Research Director, Department of Psychiatry & Neurology
Veterinarian, Department of Clinical Investigation
Medical Center Judge Advocate
Chief, Nuclear Medicine Service
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Chief, Medical Records Administration Section

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Signal Center Representative, Ft Gordon, Georgia

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PRESENTATIONS FY 92

DEPARTMENT OF CLINICAL INVESTIGATION

Morse BC, Chuang AH, Runner RR, McPehrson JC III, McPherson JC Jr: Thermal shock (cold shock) of red blood cells from mini-pigs, rats and old bank blood. AM Soc Zoologists, Atlanta, GA, 27-30 Dec 1991. (C)

Chuang AH, McPherson JC III, McPherson JC Jr: Hemolytic effect of sodium fluoride. Ann Mtg FACEBS, Anaheim, CA, 5-9 Apr 1992. (C)

Shahan MH, Chuang AH, McPherson JC III, McPherson JC Jr: Pluronic F-68 and early incisional wound healing. Ann Mtg Wound Healing Soc, Richmond, VA, 23-26 Apr 1992. (C)

Calton WC, Turgeon D, Best N, Byrne MP, Martindale RG: The effect of pentoxifylline on endotoxin mediated bacterial translocation. Gary P. Wratten

Paustian PW, McPherson JC III, McPherson JC Jr: Pluronic F-68 and early burn wound healing. Ann Mtg Wound Healing Soc, Richmond, VA, 23-26 Apr 1992. (C)

Riel MA, McPherson JC, Runner RR, Plowman KM, AHaburchak DR: Effect of intravenously administered pluronic F-127 on sunburn in the rat. GA Chap Am Coll Phy, St Simon's Island, GA, 15-16 May 1992. Assn Mil Osteo Phy Surg, Scottsdale, AZ, Apr 1992. (C)

Fowler SR, Chuang AH, McPherson JC III, McPherson JC Jr: Oleic acid induced lung edema. Ann Mtg GA Acad Sci, Statesboro, GA, 1-2 May 1992. (C)

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DENTAL ACTIVITY

Lanier L: Wear and cutting efficiency of sonic files, Am Assn Endodontists, San Francisco, CA, 8 May 1992. (C)

Primack PD: Extrusion of endodontically treated teeth. Am Assn Endodontists, San Francisco, CA, 7 May 1992.

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Schneck DL: Indications for antibiotic therapy. SE Oral Maxillofacial Surg Residents Workshop. MCG, Augusta, GA, 1 May 1992.

Olsen WL: Chronic osteomyelitis of the mandible. SE Oral Maxillofacial Surg Residents Workshop. MCG, Augusta, GA, 2 May 1992.

DEPARTMENT OF FAMILY PRACTICE

Blount BW: The military family. Uniform Svc Acad Fam Phy, Oakland, CA, May 1992.

Blount BW: Time management. Uniform Svc Acad Fam Phy, Oakland, CA, May 1992.

Blount BW: Sexually transmitted disease update. Am Acad Fam Phy, Washington, DC, Oct 1991.

Blount BW: A comparison of Family Practice content: Army to civilian. Am Acad Fam Phy, Washington, DC, Oct 1991.

Carroll D: Immunizations update. Uniform Svcs Acad Fam Phy, Oakland, CA, May 1992.

Liebert B: Community oriented primary care. Uniform Svcs Acad Fam Phy, Oakland, CA, May 1992.

Carroll D: Preventive medicine aspects of Hurricane Andrew. Army Prev Med Off Short Course, Falls Church, VA, 25 Sep 1992.

Wright GW: Using a computer prescribing system as an instructional tool. UNC Faculty Development Symposium, Chapel Hill, NC, 17-18 Jun 1992.

Smith WA, Worthy DA, Phelps KS, Rupp PJ: Prevalence of exercise induced bronchospasm in military personnel. Uniform Svcs Acad Fam Phy, Oakland, CA, 11 May 1992. (C)

Ellis D: Infectious agents present in patients with inflammatory pap smears. Uniformed Svcs Acad Family Phys, Oakland, CA, 11-15 May 1992.

LeClair B: Utilization, access and continuity of care in family practice and non-family practice military retirees. Uniformed Svcs Acad Family Phys, Oakland, CA, 11-15 May 1992.

DEPARTMENT OF MEDICINE

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Hilburn RB: Pilot study of silent myocardial ischemia and vasoactive rheumatic disease. Am Coll Phys, San Francisco, CA, 24-28 Oct 1991. (C)

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Rave MA, Matthews EA, Wilkin JA, Whitsitt TB, Plowman KM, Rebecca GS: Comparison of electrocardiographic exercise stress test features with silent ischemia monitoring in patients with angiographically normal or minimally diseased coronary arteries. Army Am Coll Phys, San Francisco, CA, Oct 1991. (C)

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DEPARTMENT OF PATHOLOGY

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Wozniak A, Goodhue WW, Yarde-Baker H, Green J, Brewer PD: The correlation of acid fast bacteria direct smear exams with AFB cultures using sputa from undiagnosed patients. Ann Postgrad Pathol Symposium, MCG, Augusta, GA, 24-25 Apr 1992.

Shikle JF, Vasallo PO: Ganglioneuromatosis and schwannoma of the small bowel. Qtrly Mtg Augusta Regional Soc Pathol, Augusta, GA, 28 May 1992.

Matlock JP, Sen JK, Brewer PD: Monocytoid B-cell lymphoma. Ann MCG

Postgraduate Pathol Symposium, Augusta, GA, 25-26 Apr 1992.

Romero N, Sen JK: Pleomorphic multiple myeloma. Ann MCG Postgraduate Pathol Symposium, Augusta, GA, 25-26 Apr 1992.

Goodhue WW: Congenital heart disease. MCG Core Curriculum Second Year Medical Student Class, Augusta, GA, 31 Aug 1992.

Sen JK: Anaplastic large cell lymphoma, Ki-1 positive, coexistent with small cleaved lymphocytic lymphoma, follicular. Augusta Reg Soc Pathol, Augusta, GA, 5 Mar 1992.

PHARMACY SERVICE

Smith D, Kottas M: Enteral feeding during therapy. ASPEN, Orlando, FL 19-22 Jun 1992.

DEPARTMENT OF PSYCHIATRY & NEUROLOGY

Perrotta C, Randle CD: The prevalence of psychiatric diagnoses in medical and surgical patients evacuated from Desert Storm. Am Psy Assn Natl Conv, Washington, DC, May 1992. (C)

Schenk DE, Perrotta C, Williford JS: Fluoxetine versus placebo in the treatment of late luteal phase dysphoric disorder. Am Psy Assn Natl Conv, Washington, DC, May 1992. (C)

Williford JS, Perrotta C, Schenk DH: The relationship of luteinizing hormone, serotonin, and pain symptoms in women with late luteal phase dysphoric disorder. Am Psy Assn Natl Conv, Washington, DC, May 1992. (C)

Schenk DE: Occult awareness workshop. US Army Garrison, Panama, 21-23 Sep 1992.

Ruck DC: Army combat. Child Psych Conf, Tacoma, WA, Nov 1991.

Ruck DC: OM team/consultation team functioning in Saudi Arabia. VA Conf Operation Desert Shield/Storm. Augusta, GA, Nov 1991.

DEPARTMENT OF SURGERY

Kaiser WL, Ramirez MF: Transient blindness and associated global amnesia following cerebral angiograph. Gary P. Wratten Surg Symposium, 1-2 Apr 1992.

Kaiser WL, Marley KR, Byrne MP, Martindale RG: Prospective evaluation of enteral feeding during somatostatin therapy. Gary P. Wratten Surg Symposium, 1-2 Apr 1992.

Calton WC, Turgeon D, Best N, Byrne MP, Martindale RG: The effect of pentoxifylline on endotoxin mediated bacterial translocation. Gary P. Wratten Surg Symposium, 1-2 Apr 1992.

Swann SW, LePage PA, Modesto VL: The use of passive drainage in breast biopsies. Gary P. Wratten Surg Symposium, 1-2 Apr 1992.

Tippens JK: Lessons learned - Orthopaedic mobilization for Operation Desert Storm. SOMOS, El Paso, TX, 16-21 Nov 1991.

Tippens JK: A medical center's response to Operation Desert Shield. SOMOS, El Paso, TX, 16-21 Nov 1991.

Erpelding JM, Tippens JK: U.S. Army operational orthopaedic surgery. SOMOS, El Paso, TX, 16-21 Nov 1991.

Barja RH, Hartley MC: The 350th EVAC hospital, Saudi Arabia. SOMOS, El Paso, TX, 16-21 Nov 1991.

Erpelding JM: A retrospective analysis of open wounds and fractures sustained during Operation Just Cause: Clinical and microbiological considerations. SOMOS, El Paso, TX, 16-21 Nov 1991.

Hartley MC, Barja RH: External fixation during Operation Desert Storm: The Howmedica Ultra-X. SOMOS, El Paso, TX, 16-21 Nov 1991.

Cutting PJ, Erpelding JM: A retrospective review of patients returning from Operation Desert Storm: The Dwight David Eisenhower Army Medical Center experience. SOMOS, El Paso, TX, 16-21 Nov 1991.

Taylor RB, Erpelding JM: Treatment of comminuted subtrochanteric femur fractures in a young population with intramedullary reconstruction nail. SOMOS, El Paso, TX, 16-21 Nov 1991.

Herzwurm PJ, Erpelding JM: Strength comparison of field external fixators: SOMOS, El Paso, TX, 16-21 Nov 1991.

Barja RH, Oettinger JM: Epiphysiodesis in rabbits by the cryoprobe method, experimental: A preliminary report. SOMOS, El Paso, TX, 16-21 Nov 1991. (C)

Kulik SA: Synatomic (Depuy) uncemented total knee arthroplasty. SOMOS, El Paso, TX, 16-21 Nov 1991.

Erpelding JM: Open tibia fractures: Classification and role of external fixation. Ann SE Region Fracture Symposium, High Point, NC, Jan 1992.

Erpelding JM: Evaluation and management of the true orthopaedic emergencies. 12th Ann U.S. Army PA Refresher Course, Apr 1992.

Erpelding JM: Common sports injuries: Initial diagnosis and treatment. 1992 Walleye Meet, Glasgow, MT Jul 1992.

Weiler HM: The intrarater and interrater reliability of the EDI-320 in measuring lumbar lordosis and trunk range of motion. Am Physical Therapy Assn Conf, Denver, CO, 18 Jun 1992.

Modesto VL, Davies R, Satava RM: Surgery in Desert Storm. SOMOS, El Paso, TX, 16-21 Nov 1991.

Modesto VL, Davies RS, Satava RM: An evacuation hospital's experience in Operation Desert Storm. Am College Surg, Chicago, IL, 20-24 Oct 1991.

Martindale R, Kaiser W: Prospective evaluation of enteral feeding during somatostatin therapy. Am Coll Surg, Georgia Chapter Mtg, Sea Island, GA, Mar 1992. (C)

Calton WC, Martindale RG: Effects of pentoxifylline on endotoxin induced bacterial translocation. Gary P. Wratten Surg Symposium, Washington, DC, Apr 1992. (C)

Scott EW: Transcervical approach to the craniovertebral junction. Ann Spine Workshop, USUSH, Bethesda, MD, 11 Jun 1992.

Beck RA: Retreat of *Haemophilus influenzae* type B: Analysis of an immunization program and implications for OTO-HNS. Ann Mtg PCOOS, Jun 1992.

Beck RA: Retreat of *Haemophilus influenzae* type B: Analysis of an immunization program and implications for OTO-HNS. Ann Mtg Am Acad OTO-HNS, Sep 1992.

Beck RA: Tumefactive fibroinflammatory lesion of pterygomaxillary space. Ann Mtg Am Acad OTO-HNS, Sep 1992.

Beck RA: Creation of a knowledge base in facial plastic and reconstructive surgery. Am Acad Facial Plastic Reconstructive Surg, Sep 1992.

DETAIL SUMMARY SHEETS

DETAIL SUMMARY SHEET

Date: 9 Oct 92		Protocol #: 84-50		Status: Completed	
Title: A scanning and transmission electron microscopic study of the effects of cadmium on the early developmental components of the craniofacial region of the hamster embryo					
Start Date: Jul 84			Est. Compl. Date:		
Principal Investigator(s): Jack A. Horner, BS Thomas F. Gale, PhD			Facility: Eisenhower Army Medical Center Medical College of Georgia		
Department/Service: Clinical Investigation Anatomy Dept, MCG			Associate Investigators:		
Key Words: Electron microscopy, Cadmium, Teratology					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective: To utilize electron microscopy to compare the fine structural features of the component tissues of 13 different regions of the face at selected timed-intervals during the early development of the craniofacial region in cadmium-exposed vs control hamster embryos.

Technical Approach: Cadmium sulfate solution is injected (IV) into timed pregnant golden hamsters on the eighth gestation day (8 AM) and embryos are collected at selected times during the period of early facial development, i.e., day 8 at 6PM; day 9 at 8AM; day 10 at 8AM; day 10 at 6PM; day 11 at 8AM. The embryos are fixed, dehydrated by critical point drying, coated with gold, and examined and photographed in the scanning electron microscope. Comparisons between embryos from the control (sham-injected) and experimental (cadmium-injected) pregnant hamsters will reveal the teratogenic effects of cadmium on the developing embryonic face. The comparisons will be both qualitative and quantitative. Collection of the quantitative data on surface area measurements will be accomplished by utilization of a computer interfaced morphometric digitometer system.

Progress: Completed.

DETAIL SUMMARY SHEET

Date: 7 Oct 92		Protocol #: 87-16		Status: Ongoing	
Title: The utility of the 50-kilodalton oncofetal tumor marker in the monitoring of treatment of cancer patients					
Start Date:			Est. Compl. Date:		
Principal Investigator(s): Donald E. Sutherland, PhD, MAJ, MS			Facility: Eisenhower Army Medical Center		
Department/Service: Clinical Investigation, Surgery					
Key Words:			Associate Investigator(s):		
			Periodic Review Results: Sep 92 Continue		
Accumulative MEDCASE Cost:					

Study Objective: To determine if the 60-kilodalton tumor marker is effective in monitoring the tumor status of patients with various types of cancer by determination of its activity post-surgery.

Technical Approach: Patients undergoing surgery for colon, breast, and lung cancer, and melanoma will have plasma drawn prior to surgery and 48 and 72 hours after surgery. The 60-kilodalton oncofetal tumor marker will be determined in all specimens and compared with results obtained in healthy volunteers. If possible, cancer patients will have plasma drawn and assays run on followup examinations, three to six months after surgery.

Total number of subjects enrolled to date: 73

Total number of subjects enrolled for reporting period: 22

Progress: With the addition of a Research Nurse Coordinator to the DCI staff and the placing of the 60-kilodalton tumor marker on the CHCS menu, specimens which had previously been lost in the shuffle are now being obtained. In the past, often only one or two specimens would be obtained from each patient. We now have 22 new patients, 11 of which have pre-op, 24- and 72-hour post-op, and at least 1 long term followup sample. Six others are awaiting the long-term followup sample. We are waiting now for funds to purchase rats to perform the 6-kilodalton assays.

DETAIL SUMMARY SHEET

Date:	Protocol #: 87-40	Status: Ongoing
Title: Pathology applications of x-ray spectrometric microanalysis		
Start Date:		Est. Compl. Date:
Principal Investigator(s): Jack A. Horner, BS		Facility: Eisenhower Army Medical Center
Department/Service: Clinical Investigation/Pathology		Associate Investigators: Phyllis Brewer
Key Words:		
Accumulative MEDCASE Cost:		Periodic Review Results:

Study Objective: To utilize specimens obtained during routine surgical and autopsy pathology examinations to gain expertise in applications of x-ray spectrometric microanalysis.

Technical Approach: Tissue specimens without known abnormalities of elemental composition are selected from the daily laboratory workload. These are examined for establishment of baseline spectrometric spectra following the use of various fixatives. These spectra can then be compared against specimens with known or suspected elemental abnormalities.

Progress:

DETAIL SUMMARY SHEET

Date:	13 Oct 92	Protocol #:	89-14	Status:	Completed
Title:	The capsule of <i>S. aureus</i> : Bone tropism, adherence and host immunity (rat model)				
Start Date:			Est. Compl. Date:	May 92	
Principal Investigator(s):	Kent M. Plowman, MD, PhD, COL, MC		Facility:	Eisenhower Army Medical Center	
Department/Service:	Infectious Disease, MCG: Clinical Investigation; Research Dept, VA		Associate Investigators:	J.P. Rissing, MD, VAMC Gary K. Best, PhD, MCG Jack A. Horner, BS Thomas Buxton, PhD	
Key Words:	Osteomyelitis, <i>S. aureus</i> , Bacterial capsule				
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective: Contrast laboratory strains of *S. aureus* for adherence to type 1 collagen *in vitro* and *in vivo*.

Technical Approach: Otherwise isogenic *S. aureus* strain SA-1 capsular variants will be compared for collagen adherence using the 125-I-collagen adherence assay. A second assay measures *S. aureus* adherence to demineralized bone. We will examine capsular variants for colonization of traumatized rat tibiae using our experimental model.

Progress: *Staphylococcus aureus* binding to exposed collagen may enhance infection in certain tissues, e.g., long bone. Clinical isolates of *S. aureus* from a variety of infections and colonization sites were assessed for their ability to bind type I collagen. In addition, the ability of a single pathogen, isolated from human osteomyelitic bone, to bind collagen was studied in detail. An attempt was made to discern the nature of ligands, in bone, bound by cells of the bone pathogen. To do this, an isogenic mutant with a reduced ability to bind type I collagen was created using transposon mutagenesis. In DNA analysis, the mutant had *Tn551* inserted into its chromosomal DNA. Conversely, cells of the parent strain were nonreactive for transposon. Using comparative analysis of SDS-PAGE profiles of adsorbed bacteria, exposed to isolated bone-matrix proteins, it was shown that collagen $\alpha 1$ -chains were bound preferentially by parent cells. The mutant had approximately one-third the affinity of the parent for type I collagen. This approach to studies of staphylococcal tissue-tropism, via specific adherence, may improve our understanding of how bone infections are initiated by this important pathogen.

DETAIL SUMMARY SHEET

Date:	7 Oct 92	Protocol #:	89-17	Status:	Terminated
Title:	Pilot study: Determination of the potential of carcinoma cells grown in culture as a source of the 60-kilodalton oncofetal tumor marker				
Start Date:	Apr 89	Est. Compl. Date:			
Principal Investigator(s):	Donald E. Sutherland, PhD, MAJ, MS		Facility: Eisenhower Army Medical Center		
Department/Service:	Clinical Investigation		Associate Investigators:		
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective: Attempt to identify carcinoma cells grown in suspension culture as a good source of SW60.

Technical Approach: Various subcultures of carcinoma cells obtained from the American Type Culture Collection will be grown in culture and the spent medium tested for SW60 by traditional methods. Cells which demonstrate secretion of SW60 will be held for future scale-up procedures to "manufacture" SW60.

Progress: No new progress has been made on this protocol. Terminate per PI.

DETAIL SUMMARY SHEET

Date: 24 Sep 92		Protocol #: 89-38		Status: Ongoing	
Title: Non-ionic surfactants in the treatment of third degree burns in rats					
Start Date: Jul 89			Est. Compl. Date:		
Principal Investigator(s): James C. McPherson III, PhD			Facility: Eisenhower Army Medical Center		
Department/Service: Clinical Investigation					
Key Words: Surfactant Burn treatment			Associate Investigators: James C. McPherson, Jr., MD Kent M. Plowman, MD, COL, MC Paul W. Paustian, MD Royce R. Runner, MT (ASCP)		
			Periodic Review Results: Sep 92 Continue		
Accumulative MEDCASE Cost:					

Study Objective: To study potential protective effects on non-ionic surfactants in the treatment of third degree burns.

Technical Approach: Effect of single and multiple doses of non-ionic surfactants given IV thirty minutes following a full thickness burn will be studied to evaluate burn wound healing.

Progress: Pluronic polyols appear to act to preserve the viability and function of the tissues surrounding a third degree burn and also act to provide an increased degree of protection into the burn injury itself. They may be able to slow or halt progressive destruction of the tissues which may occur for some time post burn and act to maintain the vascular integrity in the microcirculation for some distance into the burn by membrane actions resulting in a reversal of the increased microvascular permeability (edema). Significant reductions in edema formation have been measured in the burn area itself.

DETAIL SUMMARY SHEET

Date: 24 Sep 92		Protocol #: 89-46		Status: Ongoing	
Title: Effects of non-ionic surfactants in sunburns using a rat model					
Start Date:			Est. Compl. Date:		
Principal Investigator(s): Michael S. Riel, MAJ, MC			Facility: Eisenhower Army Medical Center		
Department/Service: Clinical Investigation					
Key Words: Sunburn Pluronic polyols			Associate Investigators: James C. McPherson, III, PhD James C. McPherson, Jr., MD Paul W. Paustian, MC Royce R. Runner, ASCP		
Accumulative MEDCASE Cost:			Periodic Review Results: Sep 92 Continue		

Study Objective: To evaluate possible protective effects of non-ionic surfactants in ultraviolet induced first degree skin burns using an albino rat model.

Technical Approach: Male, Sprague-Dawley rats weighing greater than 320 gm will be used. A 3x6 cm area will be exposed to UV light at 3x the minimal erythema dose. This study is based on earlier work which showed that the non-ionic surfactant F-127 injected shortly after a full thickness burn of the skin could reduce the amount of damage to the underlying tissue and speed healing. The mechanism of this protective effect is not yet known. This study is an attempt to isolate the steps in the process by examining first degree burns to see if these same protective effects would also work with skin which is merely injured.

Progress: Completed pilot project. Results presented at ACP Accosiates of Georga, DDEAMC Resident Research Day, and won Admiral Eske Award at AMOPS. No erythema develops in the albino rat model. Will determine minimum burn dose for rats.

DETAIL SUMMARY SHEET

Date: 28 Sep 92		Protocol #: 91-18		Status: Ongoing	
Title: Effects of different methods of hair removal on the measurement of skin blood flow in the rat using a Doppler laser blood perfusion monitor and the effect of elevated body core temperature on skin blood flow					
Start Date: Dec 90			Est. Compl. Date:		
Principal Investigator(s): James C. McPherson III, PhD			Facility: Eisenhower Army Medical Center		
Department/Service: Clinical Investigation					
Key Words: Blood flow			Associate Investigators: A. Henry Chuang, PhD Royce R. Runner, ASCP Paul W. Paustian, MD James C. McPherson, Jr, MD		
			Periodic Review Results: Sep 92 Continue		
Accumulative MEDCASE Cost:					

Study Objective: To determine the best method for hair removal from a rat in order to accurately measure blood flow and to determine if skin blood flow is altered by increasing the body core temperature.

Technical Approach: Hair will be removed by clipping (current method), surgical clipping, wet shaving or chemical removal. Skin blood flow will be measured using a Doppler laser flow technique. Increased body core temperature effect on skin blood flow will be measured.

Progress: A second blood flow monitor has been purchased to measure blood flow at a distant control site and an experimental site simultaneously. A resident has expressed interest in completing this project.

DETAIL SUMMARY SHEET

Date:	28 Sep 92	Protocol #:	91-19	Status:	Ongoing
Title:	Development of a heatstroke model in the rat and treatment with pluronic polyols				
Start Date:	Jan 91	Est. Compl. Date:	Jan 93		
Principal Investigator(s):	James C. McPherson III, PhD		Facility:	Eisenhower Army Medical Center	
Department/Service:	Clinical Investigation		Associate Investigators:	A. Henry Chuang, PhD Paul W. Paustian, MD James C. McPherson Jr, MD	
Key Words:	Heat stroke Pluronic polyols				
Accumulative MEDCASE Cost:			Periodic Review Results:	Sep 92 Continue	

Study Objective: To evaluate a new model for the production of heatstroke in the rat that will be more consistent in pathophysical parameters, will require less time to develop and will control the biological variation in the model. It will also study the effect of treatment of two pluronic polyols versus saline as the resuscitative fluid in heatstroke victims (in this case rats).

Technical Approach: Fur will be removed from the rat and the rat allowed to swim in a heated water bath. Pluronic polyol solutions and saline will be administered as resuscitative fluids. The pluronic polyols have been shown by investigators in this laboratory to have membrane protective properties.

Progress: Supplies necessary to complete this protocol have been purchased.

DETAIL SUMMARY SHEET

Date:	6 Oct 92	Protocol #:	91-24	Status:	Ongoing
Title:	Derivation and characterization of human periodontal ligament fibroblasts				
Start Date:	Jan 91	Est. Compl. Date:	Jan 93		
Principal Investigator(s): James C. McPherson III, PhD	Facility: Eisenhower Army Medical Center				
Department/Service: Clinical Investigation	Associate Investigators: Royce R. Runner Robert B. O'Neal, COL, DC William A. Brennan, COL, DC Thomas E. Van Dyke, DDS				
Key Words: Periodontal ligament Tissue culture					
Accumulative MEDCASE Cost:	Periodic Review Results:				

Study Objective: To establish human periodontal ligament fibroblasts in tissue culture, characterize the cells and investigate differences between human periodontal ligament fibroblasts and human gingival fibroblasts.

Technical Approach: Fibroblast-like cells will be removed from freshly extracted teeth containing the periodontal ligament and grown in tissue culture using techniques specifically developed to isolate and grow the periodontal ligament fibroblasts.

Progress: Initial studies are underway to harvest and initiate the primary cultures from which the periodontal ligament fibroblasts will be isolated. This protocol has taken a new interest and importance from the Periodontal Department.

DETAIL SUMMARY SHEET

Date:	28 Sep 92	Protocol #:	91-37	Status:	Ongoing
Title:	The effect of pluronic polyols on experimental edema produced by various means: Arachidonic acid, carrageenin histamine and thermal injury a study in rats and mice				
Start Date:	Jan 91	Est. Compl. Date:	Jan 93		
Principal Investigator(s):	James C. McPherson III, PhD		Facility:	Eisenhower Army Medical Center	
Department/Service:	Clinical Investigation		Associate Investigators:	Royce R. Runner, ASCP A. Henry Chaung, PhD Paul W. Paustian, MD James C. McPherson Jr, MD	
Key Words:	Edema Pluronic polyols				
Accumulative MEDCASE Cost:			Periodic Review Results:	Sep 92 Continue	

Study Objective: Previous investigations in this laboratory supported decreased skin edema in third degree burns. In this study we will investigate both pre- and post-injury IV administration of pluronic polyols on ear, skin and paw edema.

Technical Approach: Ear edema will be produced by topical application of the edema causing agents. Paw edema will be produced by injection of the edema causing agents into the foot pad and by thermal injury. Intradermal and topical applications of these agents will be used on the skin. Both pre- and post-injury IV administration of pluronic polyols will be utilized. Edema formation will be measured over time using a fluid displacement method for the paw and a micrometer caliper for the ear.

Progress: Initial experimenta have been completed to evaluate the proposed techniques. Initial results indicate that pluronic F-68 is capable of decaying and blunting the initial edema formation resulting from trauma.

DETAIL SUMMARY SHEET

Date:	23 Sep 92	Protocol #:	91-74	Status:	Ongoing
Title:	The effect of etidronate in the treatment of acute/chronic osteomyelitis in the rat tibial model				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	David W. Craft, MAJ, MS		Facility:	Eisenhower Army Medical Center	
Department/Service:	Clinical Investigation/Pathology		Associate Investigators:	Donald E. Sutherland, PhD, MAJ, MS Tu H. Nguyen, MD, LTC, MC Norma Best T.B. Buxton, PhD Jack Horner	
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:	Sep 91 continue	

Objective: To investigate the effect of etidronate in the treatment of staphylococcal acute/chronic osteomyelitis in an experimental model.

Technical approach:

Progress: We established the ID₅₀ at 1x10⁵ organisms/tibia in etidronate-treated and control animals using *Staphylococcus aureus* SMH. We also studied the effects of two levels of etidronate on the development of chronic osteomyelitis in the rat tibial model after infection with *S. aureus* SMH. X-rays were performed on both infected tibiae and contralateral controls at 21 and 49 days and are presently being evaluated. Both infected and control tibiae have been stored at -100° for future bone strength tests using the Instron unit. Tibiae were also saved from all test groups for extensive histological studies.

DETAIL SUMMARY SHEET

Date:	23 Sep 92	Protocol #:	92-15	Status:	Ongoing
Title:	Cell membranes and the gastric mucosa from sodium fluoride in the rat				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	A. Henry Chuang, PhD		Facility:	Eisenhower Army Medical Center	
Department/Service:	Clinical Investigation		Associate Investigators:	James C. McPherson III, PhD Royce R. Runner James C. McPherson, Jr., MD	
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:	Sep 92 continue	

Objective: To investigate the effects of fluoride ion on red blood cells and the gastric mucosa in the rat. Also to evaluate the effects of pluronic polyols when the red blood cells and the rats are treated with sodium fluoride.

Technical Approach: Fresh heparinized rat red blood cells will be incubated in buffered isotonic sodium chloride and sodium fluoride solutions with or without the presence of pluronic polyol, F-68. At various time intervals the percent of hemolysis of red blood cells will be determined. Sodium fluoride solutions will be administered orally to the rats. The stomach and small intestine from the rats treated orally or IV with pluronic polyol, F-127 will be compared with those without F-127.

Progress: The results of the *in vitro* study demonstrated the fluoride ion had a hemolytic action on rat red blood cells even when in buffered isotonic solutions and such effect was biphasic in nature. Pluronic polyol, F-68 at 1.2mM had a marked protective property on the hemolytic effect of fluoride. The *in vivo* study of acute fluoride activity to gastric mucosal damage showed that 10% F-127 appeared to enhance the fluoride's harmful effect on the rat digestive tract.

DETAIL SUMMARY SHEET

Date:	7 Oct 92	Protocol #:	92-53	Status:	Ongoing
Title:	A study of p53 in the plasma of patients in stages II - VI of human immunodeficiency virus (HIV-1) infection				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	Donald E. Sutherland, PhD, MAJ, MS		Facility:	Eisenhower Army Medical Center	
Department/Service:	Clinical Investigation, Medicine		Associate Investigators:	Daniel B Craig, COL, MC	
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective: To determine if p53 appears and/or increases in the plasma of HIV-seropositive patients in stages II through VI of the disease.

Technical Approach: Plasma specimens will be drawn from HIV-positive patients in Stages II-VI of the disease and tested for mutant p53 protein by a specific ELISA technique. Patients who progress to a higher level may be asked for additional samples.

Subjects enrolled to date: 0

Progress: This protocol was recently approved. Coordination has begun with COL Craig to begin collecting samples.

DETAIL SUMMARY SHEET

Date:	13 Oct 92	Protocol #:	91-3	Status:	Completed
Title:	An <i>in vivo</i> study of dentinal tubule occlusion by ferric oxalate				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	William E. Dragolich, MAJ, DC		Facility:	Eisenhower Army Medical Center	
Department/Service:	Dental Activity/Periodontic		Associate Investigators:	Robert B. O'Neal, COL, DC Scott L. Strong, LTC, DC William Brennan, COL, DC Thomas E. Van Dyke, DDS Jack A. Horner	
Key Words:	Dentin, Sensitive/anatomy, Sensitive/therapy, Sensitive/physiology				
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective: To examine the occlusion of radicular dentinal tubules by ferric oxalate.

Technical Approach: A smear layer was created on the root surface of recently extracted teeth. Ferric oxalate was then applied to the root surface in the presence of the smear layer or after its removal. The smear layer was treated by sonication, EDTA, tetracycline, and citric acid. The treated samples were then examined by SEM.

Progress: The results indicate that a decrease in the number of small crystals occurs following pretreatment of the smear layer by chemical means. An increased variability in size and shape of the crystals is also observed when no chemical pretreatment is used. Apparently, removal of the smear layer with chemicals decreases the number of available ions that may interact with ferric oxalate and thus decreases the number of precipitates. Thus, relative to the number of crystals that form, no chemical pretreatment of radicular dentin is indicated prior to application of ferric oxalate in the treatment of root sensitivity.

DETAIL SUMMARY SHEET

Date:	13 Oct 92	Protocol #:	91-4	Status:	Completed
Title:	The effects of topically applied non-ionic surfactants F-68 and F-127 on wound healing				
Start Date:	Dec 90	Est. Compl. Date:			
Principal Investigator(s):	Michael H. Shahan, MAJ, DC		Facility: Eisenhower Army Medical Center		
Department/Service:	Clinical Investigation Dental Activity/Periodontics		Associate Investigators: Scott L. Strong, LTC, DC Robert B. O'Neal, COL, DC William A. Brannan, COL, DC James C. McPherson III, PhD Thomas Van Dyke, DDS		
Key Words:	Periodontal diseases/surgery, Macrophage Chlorhexidine, Wound healing, Fibroblasts				
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective: To assess the effects of topically applied non-ionic surfactants F-68 and F-127 on surgical wounds of the rat.

Technical Approach: Study will consist of five experimental groups. Treatment medicaments appropriate to each study group will be applied to the wound site and the wound will be closed with 4/0 silk sutures placed at 1/2 cm intervals. Following the surgical procedure the animals will receive appropriate analgesics based on observed behavior. Photography will be used to document the surgical procedures.

Progress: Chlorhexidine has been used as a mouth rinse to reduce plaque accumulation in periodontal surgery patients. Standardized transdermal incisions were made on each lateral abdominal wall of 40 Sprague-Dawley rats. Wounds were irrigated with 10 ml of 0.12% chlorhexidine or 10 ml of normal saline prior to closure. Animals were sacrificed at 48 hours and 96 hours, and the wound areas were excised by a standardized protocol. Wound strength was measured using constant speed tensiometry to determine the tensile strength of the healing incision. Results revealed a significantly reduced tensile wound strength at 48 hours for the chlorhexidine treated group (127 ± 12.5 gm) compared to the saline irrigation group (150 ± 32 gm) ($p < 0.001$). However, by 96 hours a significantly increased tensile wound strength was demonstrated by the chlorhexidine treated group ($202. \pm 21$ gm) compared to the saline irrigation group (183.2 ± 37 gm) ($p < 0.05$). These data suggest that chlorhexidine irrigation of wounds produce a reduced early tensile wound strength, but ultimately resulted in shorter healing time.

DETAIL SUMMARY SHEET

Date:	13 Oct 92	Protocol #:	91-5	Status:	Completed
Title:	The effects of <i>Bacteroides gingivalis</i> endotoxin and plasma protein called "endotoxin inactivator" on gingival fibroblast attachment to surfaces <i>in vitro</i>				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	Paul Jackson, MAJ, DC		Facility:	Eisenhower Army Medical Center	
Department/Service:	Dental Activity/Periodontics		Associate Investigators:	Robert B. O'Neal, COL, DC William A. Brennan, COL, DC Scott L. Strong, LTC, DC Donald E. Sutherland, PhD, MAJ, MS Thomas E. Van Dyke, DDS	
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective: To study the effect of *P. gingivalis* endotoxin on human gingival fibroblast (HGF) attachment to human root surfaces *in vitro*. "Endotoxin inactivator" will not be evaluated in this study due to difficulties in securing sufficient quantities from the supplier.

Technical Approach: Incubate prepared root slices with either *P. gingivalis*, *E. coli* (positive control), or culture media (negative control). Allow 3H labelled HGFs to attach to treated root slices and then evaluate effects on attachment using cell counts and scanning electron microscopy.

Progress: This *in vitro* investigation has demonstrated that in plastic tissue culture wells, HGF metabolism and the later stages of attachment are inhibited by *P.gingivalis* endotoxin. However, from the study using teeth, it appears that bacterial endotoxin is readily removed from dentin surfaces and that the remaining tooth-bound endotoxin does not exert a direct inhibitory effect on HGFs.

DETAIL SUMMARY SHEET

Date:	13 Oct 92	Protocol #:	91-6	Status:	Completed
Title:	The effect of major cigarette smoke components on human gingival fibroblast reproduction				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	Mark E. Peacock, MAJ, DC		Facility:	Eisenhower Army Medical Center	
Department/Service:	Dental Activity/Periodontics		Associate Investigators:	Robert B. O'Neal, COL, DC William A. Brennan, COL, DC Scott L. Strong, LTC, DC Donald E. Sutherland, MAJ, DC Thomas E. Van Dyke, DDS	
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective: The ability of fibroblasts to reproduce and attach to teeth is of paramount importance in re-establishing the lost connective tissue attachment after periodontal therapy. Factors which can alter the tissue responses need to be examined. Studying the effect of nicotine, a component of tobacco, on fibroblast reproduction and attachment is of significance.

Technical Approach: Cell cultures of primary human gingival fibroblasts are obtained from the Medical College of Georgia School of Dentistry and utilized between passages 5 and 10. MTT, one of the tetrazolium salts, is used in a colorimetric method of determining cellular proliferation, and also in determining cell numbers that attach upon exposure to varying concentrations of nicotine. Only living cells cleave the formazan product of MTT. After solubilization, the resulting solutions will be read in a microplate reader at 570 nm.

Progress: The results of this study indicate that (1) exposure to nicotine enhances human gingival fibroblast attachment to a substrate, and this appears to be concentration-dependent; (2) mitochondrial dehydrogenase activity is transiently decreased following nicotine exposure, but by 4 hours the enzyme activity is approximately equal to control; (3) exposure to low concentrations of nicotine has a significant stimulatory effect on HGF reproduction, while the higher concentrations produce a slight increase in HGF culture growth; and, (4) the effect of nicotine upon HGF reproduction does not seem to persist following nicotine removal.

DETAIL SUMMARY SHEET

Date:	13 Oct 92	Protocol #:	91-7	Status:	Completed
Title:	Evaluation of the effect of diagnostic radiation on titanium dental implant osseointegration in micro swine				
Start Date:	Dec 90	Est. Compl. Date:			
Principal Investigator(s):	Patrick J. Basquill, MAJ, DC		Facility: Eisenhower Army Medical Center		
Department/Service:	Dental Activity/Periodontics		Associate Investigators: William A. Brennan, COL, DC Scott L. Strong, LTC, DC Robert B. O'Neal, COL, DC Thomas E. Van Dyke, DDS Jack A. Horner		
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective: To investigate the effect on osseointegration of diagnostic doses of x-radiation exposure during the healing phase of the titanium dental implant.

Technical Approach: Histological evaluation of the bone-implant interface of Branemark implant fixtures exposed to diagnostic doses of x-radiation commonly used in dentistry will be compared to controls receiving no radiographic exposure.

Progress: The results of this study revealed no detectable differences in the measured parameters. There was no statistically significant difference in contact length fractions for implants exposed to varying doses of radiation versus controls. The microvasculature in tissues adjacent to and abutting the implants was consistent regardless of whether the implant was exposed to radiation or served as a control. Standardized clinical radiographs employed to evaluate crestal alveolar responses failed to demonstrate any apparent trends in control versus radiated implants. Within the confines of the present animal study, diagnostic doses of radiation to titanium dental implants at implant placement time produced no effect on quantity or quality of bone at the implant interface after fourteen weeks of healing. The results of this study suggest that diagnostic radiation may be used at healing implant sites without any adverse effect.

DETAIL SUMMARY SHEET

Date:	5 Octo 92	Protocol #:	91-8	Status:	Completed
Title:	Pulpal response to block copolymer F-127 gel when used as a direct pulp capping agent				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):			Facility:		
Eugene West, MAJ, DC			Eisenhower Army Medical Center		
Department/Service:			Associate Investigators:		
Dental Activity/Endodontics			James C. Kulild, COL, DC		
Key Words:			Patrice D. Primack, LTC, DC		
			David Lewis, COL, DC		
			James C. McPherson III, PhD		
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective: To evaluate the effect of a block copolymer gel (F-127), with and without the addition of CH, on the pulp when placed over direct pulp caps in class V cavity preparations in deciduous pig premolars and molars.

Progress: Research completed.

DETAIL SUMMARY SHEET

Date:	5 Oct 92	Protocol #:	91-9	Status:	Ongoing
Title:	Wear and cutting efficiency of sonic files				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	Leander Lanier Sr, MAJ, DC		Facility:	Eisenhower Army Medical Center	
Department/Service:	Dental Activity/Endodontics		Associate Investigators:	James C. Kulild, COL, DC Patrice D. Primack, LTC, DC	
Key Words:				Jack A. Horner	
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective: To evaluate the wear of Shaper-sonic files after use *in vitro* in a simulated root canal in bovine bone and relate this wear to its cutting efficiency.

Technical Approach: Simulated root canals will be prepared from a single bovine femur. Forty-five specimens will be prepared 3x2x2 cm using a band saw. Three pilot holes, simulating artificial root canals, will be drilled along the 3 cm side of each block through the cortical plate completely through the 2 cm side. Three 0.6 mm diameter holes will be drilled in the first group of 15 blocks; 0.7 mm holes in the second group of 15 blocks; and 0.8 mm holes in the last group of 15 blocks. Lubricant will be used throughout the drilling procedure to prevent burning of the bone. The specimens will be maintained in a solution of 0.2% sodium azide to prevent bacterial growth.

Progress: Resident graduated, completed groups A & C but not B. He PCS'd to Ft Benning, GA. He is to return on leave to complete project but as of 28 Sep he has not done so.

DETAIL SUMMARY SHEET

Date:	24 Jun 92	Protocol #:	91-10	Status:	Completed
Title:	<i>in vitro</i> diffusion of diphosphonate through radicular dentin				
Start Date:	Oct 90	Est. Compl. Date:	May 92		
Principal Investigator(s):	David A. Galvan, MAJ, DC		Facility:	Eisenhower Army Medical Center	
Department/Service:	Dental Activity/Endodontics		Associate Investigators:	James C. Kulild, COL, DC Donald E. Sutherland, MAJ, MS Patrice D. Primack, LTC, DC	
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective: To evaluate the ability of technetium 99 labelled diphosphonate to diffuse from within the root canals of single-rooted human teeth through radicular dentin to the surface of the root.

Technical Approach: Fifteen roots will be used to determine the ability of technetium 99 labelled diphosphonate to diffuse through the radicular dentin under five experimental conditions.

Progress: Recently extracted human maxillary incisors were obtained and stored in a solution of 0.2% NaAzide and isotonic saline. The crowns of the teeth were removed 2-3 mm coronal to the CEJ. The roots were endodontically instrumented to a size #70 K-Flex endodontic file and then bonded to Plexiglas blocks, with a hole in the center, to allow access to the pulp chamber and root canal systems. The diffusion permeability of the prepared roots was evaluated using $^3\text{H}_2\text{O}$ as a radioactive tracer placed in the pulp canal space and suspending the roots in water. The water in which the roots were suspended was sampled hourly for the presence of any $^3\text{H}_2\text{O}$ activity. A diffusion plateau of $^3\text{H}_2\text{O}$ was reached in 6-7 hours. The experiment was repeated after smear layer removal with EDTA/NaOC1 and again after storage in normal saline at 4° C for 8 weeks. Results showed a statistically significant decrease in the diffusion plateau after smear layer removal and a statistically significant increase after storage in saline for 8 weeks. This indicates that removing the smear layer with EDTA/NaOC1 may decrease the intrinsic permeability of endodontically treated teeth. This decrease in permeability may be transient because the cause for the decrease in permeability may be water soluble as shown by the rise in permeability after storage for 8 weeks in water. These same roots were depth cut 1 mm on all surfaces in the middle and coronal thirds. The depth cuts were connected resulting in the removal of all of the cementum and some peripheral dentin. A solution containing ^{14}C Carbondiphosphonate was placed into the pulp canal space. The roots were suspended in water and the water sampled at 2 hour intervals for up to 36 hours. After 36 hours no ^{14}C Carbon activity could be detected, indicating that ^{14}C Carbondiphosphonate did not diffuse through radicular dentin to the external surface of the root.

DETAIL SUMMARY SHEET

Date:	24 Jun 92	Protocol #:	91-61	Status:	Completed
Title:	The effect of time delay on tensile bond strength of the silicoated and silane treated metal surface				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	Betty G. Galvan, MAJ, DC		Facility:	Eisenhower Army Medical Center	
Department/Service:	Dental Activity		Associate Investigators:	Marion J. Edge, COL, DC F. Michael Gardner, COL, DC	
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective: To test tensile bond strength of silicoated and silane treated metal surfaces at different time intervals up to 30 days.

Technical Approach: Data will be collected on tensile force required for failure in each group, and statistical analysis of the data will be conducted using a one tailed t-test analysis of variance with a moving average to determine significant differences between the test groups.

Progress: The acid etched resin bonded fixed partial denture is generally retained by micromechanical retention of the metal and tooth surfaces. An alternative metal treatment to obtain the micromechanical retention of the metal retainer is by using the Silicoater system. The tensile bond strength of this silicoated and silane treated surface was tested at various time intervals of up to 30 days. Rexillum III surfaces were silicoated, treated with silane coupling agent and stored in sealed plastic bags. Specimen pairs were bonded with Compspan at different time intervals and tested in tension. No statistically significant differences were recorded between the group. All groups recorded an acceptable average tensile bond strength of approximately 40 MPa.

DETAIL SUMMARY SHEET

Date:	6 Oct 92	Protocol #:	91-62	Status:	Ongoing
Title:	Parotid gland biopsy and transbronchial lung biopsy in the diagnosis of sarcoidosis: A comparison study				
Start Date:	Jul 91	Est. Compl. Date:			
Principal Investigator(s):	R. Terry Ellis, MAJ, DC		Facility:	Eisenhower Army Medical Center	
Department/Service:	Dentistry, Pulmonary		Associate Investigators:	Michael W. Tabor, COL, DC David M. Lewis, COL, DC William Johnson, COL, MC	
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective: To relate the involvement of the lungs and parotid gland in sarcoidosis.

Technical Approach: Patients with strong suspicion of sarcoidosis undergo open biopsy of parotid and transbronchial lung biopsy under intravenous sedation. OMS Staff or residents perform intravenous sedation and parotid gland biopsy, then transbronchial lung biopsy is performed by Pulmonary Staff physicians. Tissues are then evaluated by COL David Lewis, Staff Oral Pathologist.

Manpower: Existing clinic staff is utilized.

Number of subjects enrolled to date: 7

No adverse reactions.

Progress: Seven patients have been entered into the study. Five of the patients have been diagnosed with sarcoidosis via these biopsy techniques.

DETAIL SUMMARY SHEET

Date:	24 Jun 92	Protocol #:	91-63	Status:	Completed
Title:	An evaluation of a selective die spacer placement technique				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	Tam S. Hager, MAJ, DC		Facility:	Eisenhower Army Medical Center	
Department/Service:	Dental Activity/Prosthodontics		Associate Investigators:	M.J. Edge, COL, DC F.M. Gardner, COL, DC	
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective: To evaluate the advantage, if any, of selectively applying paint-on spacer at the occlusal line angles of laboratory dies.

Technical Approach: The seatability of metal copings fabricated from this method will be compared to those fabricated from fully coated dies. Since it has been established that binding occurs mainly at the occlusal line angles, it can be assumed that castings made from dies selectively coated in these areas will seat equally as well as those made from dies that have had all surfaces painted.

Progress: Results showed no statistical difference in seating between castings made with conventional relief and those made with additional relief at the axial-occlusal line angles. Castings relieved exclusively at the axial-occlusal line angles exhibited significant post-cementation marginal openings.

DETAIL SUMMARY SHEET

Date:	5 Oct 92	Protocol #:	91-72	Status:	Ongoing
Title:	Evaluation of heat generated when exposed titanium implant fixture threads are removed using rotary instruments				
Start Date:	Aug 91	Est. Compl. Date:	Jun 93		
Principal Investigator(s):	Facility:				
Elise F. Adrian, LTC, DC	Eisenhower Army Medical Center				
Department/Service:	Associate Investigators:				
Dental Activity	William A. Brennan, COL, DC				
Key Words:	Michael A. Billman, LTC, DC				
	Benjamin S. Hanson, LTC, DC				
		Jack A. Horner			
Accumulative MEDCASE Cost:	Periodic Review Results:				

Study Objective: To determine if the technique of recontouring fixture threads raises the temperature of the fixture surface above the critical bone temperature of 47°C.

Technical Approach: A model system will be used to monitor temperature changes along a titanium implant during mechanical removal of exposed fixture threads.

Progress: Approval has recently been given to authorize MCG biomedical engineering department to construct necessary equipment. Due to a heavy workload at clinical investigations, there was a delay in determination and construction of some of the equipment necessary for the project. In addition the support received from TSC has been less than optimal. As soon as these problems have been remedied, the project should proceed to completion.

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DETAIL SUMMARY SHEET

Date:	5 Oct 92	Protocol #:	91-73	Status:	Ongoing
Title:	Effect of nicotine on fibroblast integrin expression and distribution <i>in vitro</i>				
Start Date: Sep 91	Est. Compl. Date:		Jun 93		
Principal Investigator(s): Gregory W. Austin, MAJ, DC	Facility:		Eisenhower Army Medical Center		
Department/Service: Dental Activity/Clinical Investigation	Associate Investigators: Benjamin S. Hanson, LTC, DC Michael A. Billman, LTC, DC William A. Brennan, COL, DC Donald E. Sutherland, MAJ, MS Thomas E. Van Dyke, DDS, PhD				
Key Words:					
Accumulative MEDCASE Cost:	Periodic Review Results:				

Study Objective: To determine the effect of various concentrations of nicotine on human fibroblast integrin expression and distribution *in vitro*.

Technical Approach: The expression of Beta-1 integrin by human gingival fibroblasts incubated in different concentrations of nicotine, 0.025, 0.05, 0.1, 0.2, and 0.4 uM, is being studied utilizing a monoclonal labelled antibody utilizing flow cytometry, cytoflow, and ELISA methods.

Progress: Pilot studies have been completed in flow cytometry, ELISA, and cytoflow. Initial data has been collected using flow cytometry and is presently undergoing statistical analyses. Final ELISA testing is about to begin. Attachment studies are still in the pilot study stage utilizing the cytoflow methodology.

DETAIL SUMMARY SHEET

Date:	28 Sep 92	Protocol #:	91-75	Status:	Ongoing
Title:	Parenteral application of F-68 and F-127 surfactants to belly wounds in rats after an initial healing period of 48 and 96 hours				
Start Date:	Oct 91	Est. Compl. Date:	May 92		
Principal Investigator(s):	Ronnie K. Jones, LTC, DC		Facility:	Eisenhower Army Medical Center	
Department/Service:	Dental Activity/Clinical Investigation		Associate Investigators:	Michael A. Billman, LTC, DC William A. Brennan, COL, DC Benjamin S. Hanson, LTC, DC James C. McPherson III, PhD	
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:	Sep 92 Continue	

Study Objective: To assess the effects of parenteral application of F-68 and F-127, non-ionic surfactants, on flank wounds in rats after healing of 24 or 48 hours.

Technical Approach:

Progress: The total number of animals used the last fiscal year was approximately 300, with a balance of 64. The balance of the animals will be used the next fiscal year. The research has progressed well, with only minor problems, lost 40+ animals when the compressor stopped functioning. Histologic evaluation and the end stage of the research will be completed by the end of March 1993. An abstract has been submitted to International Association of Dental Research for evaluation.

DETAIL SUMMARY SHEET

Date:	28 Sep 92	Protocol #:	01-76	Status:	Ongoing
Title:	The effects of parenterally administered pluronic F-68 and F-127 on skin grafts in the rat				
Start Date: Jul 91			Est. Compl. Date:	Jun 93	
Principal Investigator(s): Dennis P. Akiyama, LTC, DC			Facility:	Eisenhower Army Medical Center	
Department/Service: Dental Activity/Clinical Investigation			Associate Investigators:	William A. Brennan, COL, DC Michael A. Billman, LTC, DC Benjamin S. Hanson, LTC, DC A. Henry Chaung, PhD James C. McPherson III, PhD James C. McPherson, Jr, MD	
Key Words: Rats, Skin flaps, Wound healing Pluronic polyols, Vasculariation,					
Accumulative MEDCASE Cost:			Periodic Review Results:	Sep 92 Continue	

Study Objective: To investigate the effects of parenterally administered pluronic polyols F-68 and F-127 on the healing ability of full thickness skin flaps in the rat.

Technical Approach: Histology, measurement of vascularity of flaps by injection of vital dyes.

Progress: Experimental phase, gathering data.

DETAIL SUMMARY SHEET

Date:	4 Nov 92	Protocol #:	91-77	Status:	Ongoing
Title:	Comparison of effect of citric acid conditioning <i>versus</i> tetracycline on human gingival fibroblast attachment <i>in vitro</i>				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	Eric P. Jankowski, LTC, DC		Facility:	Eisenhower Army Medical Center	
Department/Service:	Dental Activity/Clinical Investigation		Associate Investigators:	William A. Brennan, COL, DC Benjamin S. Hanson, LTC, DC Michael Billman, LTC, DC James McPherson III, PhD Royce R. Runner, ASCP	
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective: To examine and compare the effect on attachment rate and strength of attachment of human gingival fibroblasts (HGF) to dentin chips when the dentin has been conditioned using either citric acid or tetracycline.

Technical Approach:

Progress: Study ongoing, no reportable data.

DETAIL SUMMARY SHEET

Date:	6 Oct 92	Protocol #:	91-78	Status:	Ongoing
Title:	<i>in vitro</i> effect of 30% hydrogen peroxide and sodium perborate on endodontic sealers in roots obturated with gutta-percha				
Start Date:		Est. Compl. Date:	May 93		
Principal Investigator(s):	Facility:				
Gary R. Karren, LTC, DC	Eisenhower Army Medical Center				
Department/Service:	Associate Investigators:				
Dental Activity/Clinical Investigation	James C. Kulild, COL, DC				
Key Words:	Patrice D. Primack, LTC, DC				
Accumulative MEDCASE Cost:	Periodic Review Results:				

Study Objective: To determine the effect of 30% HP and SP on two root conal sealers used with gutta-percha to obturate root canals.

Technical Approach:

Progress: The study has progressed to 50% completion. It is anticipated that the laboratory portion of the study will be completed by Feb 93. The only minor modification that has been made to the protocol is the dye phase which is being performed in a vacuum environment.

DETAIL SUMMARY SHEET

Date:	5 Oct 92	Protocol #:	91-79	Status:	Completed
Title:	Fibroblast attachment to new endodontic retrofilling materials				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	Sylvester Robinson, MAJ, DC		Facility:	Eisenhower Army Medical Center	
Department/Service:	Dental Activity /Clinical Investigation		Associate Investigators:	James C. Kulild, MAJ, DC Patrice Primack, LTC, DC James C. McPherson III, PhD Donald E. Sutherland, MAJ, MS	
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective: To investigate the toxicity of five different retrofilling materials to gingival fibroblasts and also to investigate the ability of gingival fibroblasts to attach to the retrofilling materials and to examine a possible correlation between attachment and wound healing.

Technical Approach: Human gingival fibroblasts were cultured in vitro with six different retrofilling materials. Cells were labeled with radioactive uridine to evaluate RNA synthesis and metabolic impairment of the cells by the materials.

Progress: Three experiments were performed using each material individually and dental sticky wax as a control. Three longitudinal studies were done to compare the effects fo all six materials and the control. Presently evaluating the data from the 21 completed experiments.

DETAIL SUMMARY SHEET

Date:	13 Oct 92	Protocol #:	91-80	Status:	Ongoing
Title:	A comparison of the effects of bisphosphonate, gallium nitrate, and calcium hydroxide on osteoclast-like cells <i>in vitro</i> and <i>in vivo</i>				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	Frederick R. Liewehr, MAJ, DC		Facility:	Eisenhower Army Medical Center	
Department/Service:	Dental Activity/Clinical Investigation		Associate Investigators:	James C. Kulild, COL, DC David K. Turgeon, MAJ, MS Donald E. Sutherland, MAJ, MS	
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective: To investigate the ability of bisphosphonate and gallium nitrate impregnated dentin slabs to resist dentinoclastic activity *in vivo* in chick embryos and *in vitro* in tissue culture, and to introduce a simple and inexpensive experimental model which can be used for further dental *in vivo* studies of osteoclastic activity.

Technical Approach:

Progress: To date five *in vivo* and six *in vitro* studies have been completed. Numerous methodological and procedural problems have plagued our efforts, including bacterial contamination of samples, fungal contamination of an incubator, power outages resulting in embryo death, improper handling of samples by histology, broken or occupied SEM, etc. Data was difficult to interpret as the experimental designs of these pilots were destroyed by unequal destruction of samples.

After repeated attempts to refine the methodology of the *in vivo* portion, and consultations with the originator of the technique, we were forced to abandon this portion of the study due to our failure to achieve resorption.

the *in vitro* technique has been improved and is producing results. This will be the sole methodology used in the remainder of the investigation.

Currently a large pilot is under way to determine whether the experimental drugs in concentrations that approximate clinical use are effectatious. Additionally, we are investigating the use of 1.25(OH)₂ D3 to see if we can use it to cause increased differentiation of hematogenous osteoclast precursors in order to enhance our yield of these cells. Finally, we are trying the use of Ficoll-Hypaque to see if we can establish a centrifugal gradient for separating these cells from the mixture produced in our harvest.

DETAIL SUMMARY SHEET

Date:	5 Oct 92	Protocol #:	92-31	Status:	Ongoing
Title:	A clinical study of the relationship between computed tomography and bone sounding				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	Eric Adrian, LTC, DC		Facility:	Eisenhower Army Medical Center	
Department/Service:	Dental Activity		Associate Investigators:	Benjamin Hanson, LTC, DC Willaim A. Brennan, COL, DC Michael A. Billman, LTC, DC Michael W. Tabor, COL, DC Thomas Raltson, LTC, MC	
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective: The anatomic surface topology of planned implant sites as recorded by CAT Scan and the bone mapping technique will be compared for accuracy, time and cost.

Technical Approach: Through the use of a location guide stent the bone is measured using the bone map technique and the CAT Scan.

Number of subjects enrolled to date: 20

Progress: Twelve patients have been mapped and eight have been scanned.

DETAIL SUMMARY SHEET

Date:	6 Oct 92	Protocol #:	92-32	Status:	Completed
Title:	Soft tissue reactions around dental implants: A clinical study comparing split thickness skin grafts, free gingival grafts, and non-grafted alveolar mucosa/gingiva				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	Wayne L. Olsen, MAJ, DC		Facility:	Eisenhower Army Medical Center	
Department/Service:	Dental Activity		Associate Investigators:	Michael W. Tabor, COL, DC David M. Lewis, COL, DC Michael A. Billman, LTC, DC Eric Adrian, LTC, DC Benjamin Hanson, LTC, DC	
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective: To evaluate and compare soft tissue reactions around oral implants.

Technical Approach: Retrospective evaluation and questionnaire study.

Number of subjects enrolled: 16

Progress: This retrospective study involved clinically evaluating patients (16 patients/65 implant sites) as well as having them complete a subjective questionnaire which has been completed. To date there have been no complications.

DETAIL SUMMARY SHEET

Date:	27 Oct 92	Protocol #:	92-44	Status:	Ongoing
Title:	Influence of the posterior horizontal plate angle on pantographic recording of immediate side shift				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	Marcus F. McDonald, MAJ, MC		Facility:	Eisenhower Army Medical Center	
Department/Service:	Dental Activity		Associate Investigators:	Michael F. Gardner, COL, DC Max Gaston, LTC, DC	
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective:

Technical Approach:

Progress: Study ongoing, no reportable data.

DETAIL SUMMARY SHEET

Date:	27 Oct 92	Protocol #:	92-45	Status:	Ongoing
Title:	The effect of loading on the porcelain labial margin of a ceramo-metal restoration				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	Karen W. Tillman, LTC, DC		Facility:	Eisenhower Army Medical Center	
Department/Service:	Dental Activity		Associate Investigators:	Michael F. Gardner, COL, DC Max L. Gaston, LTC, DC	
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective:

Technical Approach:

Progress: Study ongoing, no reportable data.

DETAIL SUMMARY SHEET

Date:	27 Oct 92	Protocol #:	92-46	Status:	Ongoing
Title:	A comparison of impression techniques for the ceraOne abutment				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	James K. Schmitt, MAJ, DC		Facility:	Eisenhower Army Medical Center	
Department/Service:	Dental Activity		Associate Investigators:	Michael F. Gardner, COL, DC Eric Adrian, LTC, DC	
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective:

Technical Approach:

Progress: Study ongoing, no reportable data.

DETAIL SUMMARY SHEET

Date:	2 Oct 92	Protocol #:	92-56	Status:	Ongoing
Title:	A Clinical Evaluation of Autogenous Iliac Bone Grafts in Periodontal Osseous Defects				
Start Date: Jun 92			Est. Compl. Date:	Jun 94	
Principal Investigator(s): Benjamin S. Hanson, DC			Facility: Eisenhower Army Medical Center		
Department/Service: Dental Activity			Associate Investigators: William Brennan, COL, DC		
Key Words: Periodontitis, Iliac graft					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective: To investigate the feasibility of the use of autogenous frozen marrow as a treatment modality in periodontal osseous defects.

Technical Approach: Twenty patients with hopeless teeth will be asked to participate in this study. Bone will be harvested from the ilium and stored in MEM at -6 C. Seven days after the cores have been taken they will be placed in periodontal defects.

Number of subjects enrolled to date: 4

Progress: In the four patients we have treated thus far we have had excellent results.

DETAIL SUMMARY SHEET

Date:	2 Oct 92	Protocol #:	92-57	Status:	Ongoing
Title:	Evaluation of the benefits of screening tests done prior to periodontal therapy				
Start Date: Jun 92			Est. Compl. Date:	Jun 93	
Principal Investigator(s): Benjamin S. Hanson, LTC, DC			Facility: Eisenhower Army Medical Center		
Department/Service: Dental Activity			Associate Investigators: William Brennan, COL, DC		
Key Words: Screening tests					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective: To investigate the value of adjunctive screening lab tests before periodontal therapy.

Technical Approach: One hundred patients over the age of 40 will be selected at random and referred for biochemical and hematologic profiles. The tests will include CBC, UA, SMAC-17, PT, PTT, and platelet count.

Number of subjects enrolled to date: 10

Progress: No conclusions at this time.

DETAIL SUMMARY SHEET

Date:	5 Oct 92	Protocol#	92-58	Status	Ongoing
Title:	A comparison of the clinical success of the 5mm Nobelpharma implant fixture to the standard 3.75mm fixture				
Start Date:			Est. Compl. Date:	Jun 93	
Principal Investigator(s):	Eric Adrian, LTC, DC		Facility:	Eisenhower Army Medical Center	
Department/Service:	Dental Activity		Associate Investigators:		
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective: To study the clinical success of the 5mm fixture at 1, 2 and 3 year intervals.

Technical Approach: Clinical and radiological parameters will be used to compare the new fixture to the 3.75mm fixture.

Number of subjects enrolled to date: 15

Progress: To date two fixtures have been placed with no complications.

DETAIL SUMMARY SHEET

Date:	8 Oct 92	Protocol #:	92-74	Status:	Ongoing
Title:	Wear and Cutting Efficiency of the Rispi-sonic File				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	Gordon W. Woollard, MAJ, DC		Facility:	Tingay Dental Clinic	
Department/Service:	Dental Activity		Associate Investigators:		
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective: To determine the cutting efficiency of Rispi-sonic files used in a MM 1500 endosonic system.

Technical Approach:

Progress: Local approval late FY 92, no progress to report.

DETAIL SUMMARY SHEET

Date:	8 Oct 92	Protocol #:	92-75	Status:	Ongoing
Title:	The Effects of Intracanal Medicaments, Cements (sealer), and Fillers on Fibroblast Growth and Attachment to a Tooth Which has Received Root Canal Therapy				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	Lawrence G. Breault, MAJ, DC		Facility:	Tingay Dental Clinic	
Department/Service:	Dental Activity		Associate Investigators:		
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective: To investigate the effects that the placement of intracanal medicaments, fillers, and cements in endodontically treated teeth may have on periodontal regenerative procedures.

Technical Approach:

Progress: Local approval late FY 92, no progress to report.

DETAIL SUMMARY SHEET

Date:	8 Oct 92	Protocol #:	92-76	Status:	Ongoing
Title:	Endogenous Prostaglandin Induced by IL-1B and TNFa Regulates IL-6 Production by Human Gingival Fibroblasts				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	Charlene A. Czuszek, MAJ, DC		Facility:	Tingay Dental Clinic	
Department/Service:	Dental Activity		Associate Investigators:		
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective: To elucidate a mechanism by which the interaction of cytokines, such as IL-1B and TNFa, may promote IL-6 production.

Technical Approach:

Progress: Local approval late FY 92, no progress to report.

DETAIL SUMMARY SHEET

Date:	8 Oct 92	Protocol #:	92-77	Status:	Ongoing
Title:	The Effect of Transforming Growth Factor Beta (TGF-B) in Conjunction with Polyols on Wound Healing Rats				
Start Date:		Est. Compl. Date:			
Principal Investigator(s):	Facility:		Animal Support Facility,		
George E. Tolson IV, MAJ, DC			Clinical Investigation		
Department/Service:	Associate Investigators:				
Dental Activity					
Key Words:					
Accumulative MEDCASE Cost:	Periodic Review Results:				

Study Objective: To examine the effects of parenterally administered Transforming Growth Factor Beta in combination with topically applied pluronic polyols F-68 and F-127 on the tensile strength and healing of incisional wounds in the rat.

Technical Approach:

Progress: Local approval late FY 92, no progress to report.

DETAIL SUMMARY SHEET

Date:	16 Jun 92	Protocol #:	91-57	Status:	Completed
Title:	Prevalence of exercise-induced bronchospasm in active-duty army personnel				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	Wiley A. Smith, MD, MAJ, MC		Facility:	Eisenhower Army Medical Center	
Department/Service:	Family Practice		Associate Investigators:	David A. Worthy, MD, CPT, MC Karen S. Phelps, MD, CPT, MC Paul J. Rupp, MD, CPT, MC	
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective: To determine the prevalence of EIB by free running exercise testing among active duty army personnel participating in a two mile run.

Technical Approach: Pre-exercise pulmonary function testing will be performed using a portable spirometer. Subjects will then perform a standard army physical fitness test, to include pushups, situps, and finally a two mile run. Immediately after completing the run subjects will be seated, a pulse rate and the finishing time for the two-mile run recorded. Pulmonary function testing will be performed at one minute, five minutes, and ten minutes after finishing.

Number of subjects enrolled to date: 155

Number of subjects enrolled for the reporting period: 28

Progress: We found a higher prevalence of exercise induced bronchospasm in our population than in previous studies despite the fact that our cutoff scores for diagnosing EIB were higher than in some other studies. Estimates of EIB in athletes range from 2.8 to 14 percent in studies for which a 10% drop in FEV1 or PF were considered diagnostic. Our method involved a longer period of exercise than used in other studies which may partially explain the higher prevalence. Free running tests are considered more asthmogenic than treadmill or bicycle ergometer testing. Another factor could be airborne allergens present in higher concentration in outdoor air during the seasons in which most of our testing was performed, spring and fall. Our testing was performed predominantly in conditions of mild temperature and relative humidity so that the prevalence of the condition can't be attributed to cold and dry air. The three parameters we studied, FEV1, PF, and FEF25-75, yielded similar prevalence. FEV1 proved to be the most reproducible measurement and PF the least. The lack of correlation of running times or testing points earned on the run with EIB suggests that the presence of EIB is not a major determinant of running ability in our study population. This population, although not usually competitive athletes, are called upon to maintain a degree of physical conditioning. These were not recruits new to the Army so those who were unable to run well because of EIB may have been selected out by failure to complete basic training. Since EIB is quite prevalent even among well trained athletes, there is room to question what influence it has on athletic performance and what interventions are necessary. Inhaled agents such as cromolyn sodium and beta sympathomimetics are effective. There are conflicting studies on whether training to obtain physical fitness itself decreases

the severity of EIB. Whether EIB severity is decreased or not, physical training for its sufferers increases their exercise capacity. Whether treating EIB pharmacologically or non-pharmacologically would increase the fitness level of military recruits or seasoned military personnel should be studied in a controlled and randomized fashion.

DETAIL SUMMARY SHEET

Date:	5 Oct 92	Protocol #:	92-14	Status:	Ongoing
Title:	Safety and efficacy of clarithromycin and erythromycin ethylsuccinate suspensions in the treatment of children with community-acquired pneumonia				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	George W. Wright, MAJ, MC		Facility:	Eisenhower Army Medical Center	
Department/Service:	Family Practice		Associate Investigators:	Bruce M. LeClair, MAJ, MC	
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective: To compare the efficacy and safety of clarithromycin and erythromycin ethylsuccinate suspensions in the treatment of children with community-acquired pneumonia who are suitable candidates for oral macrolide therapy.

Technical Approach: Randomized, investigator blind, multicenter trial.

Subjects enrolled to date: 0

Progress: Prepared for first patients in coming pneumonia season.

DETAIL SUMMARY SHEET

Date:	27 Oct 92	Protocol #:	92-16	Status:	Ongoing
Title:	Comparison of family Apgar scores of outpatients with principal diagnoses and medication use				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	H. James Huffnagle, CPT, MC		Facility:	Eisenhower Army Medical Center	
Department/Service:	Family Practice		Associate Investigators:	Roger Bruce, LTC, MC	
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective:

Technical Approach:

Progress: No reportable data.

DETAIL SUMMARY SHEET

Date:	5 Oct 92	Protocol #:	92-24	Status:	Ongoing
Title:	The positive and negative predictive value of a routine fifty gram glucose screening test at the initial prenatal visit				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	Karen S. Phelps, CPT, MC		Facility:	Eisenhower Army Medical Center	
Department/Service:	Family Practice		Associate Investigators:	Kim DeStefano, CPT, MC	
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective: To determine usefulness of 1° glucola in all antepartum patients at first prenatal visit.

Technical Approach:

Number of subjects enrolled to date: 100

Progress: Currently data (by chart review) for pilot study.

DETAIL SUMMARY SHEET

Date:	9 Oct 92	Protocol #:	92-34	Status:	Completed
Title:	Assessment of the relationship between religiosity and well being				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	Drew A.J. Steiner, CPT, MC		Facility:	Eisenhower Army Medical Center	
Department/Service:	Family Practice		Associate Investigators:	Bruce A. Leibert, MAJ, MC Andree J. Lloyd, PhD Neil Trent, MAJ, MC	
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective: Determine our population's religiosity score and sense of well-being score.

Technical Approach: Questionnaire.

Number of subjects enrolled to date: 46

Progress: Data analysis, study completed.

DETAIL SUMMARY SHEET

Date:	27 Oct 92	Protocol #:	92-41	Status:	Ongoing
Title:	The effectiveness of interventions to increase compliance with breast cancer screening guidelines of the US task force for clinical preventive services				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	Dale Carroll, COL, MC		Facility:	Eisenhower Army Medical Center	
Department/Service:			Associate Investigators:		
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective:

Technical Approach:

Subjects enrolled to date: 0

Progress: Study on hold pending funding approval from MRDC.

DETAIL SUMMARY SHEET

Date:	2 Oct 92	Protocol #:	92-54	Status:	Ongoing
Title:	Determination of the prevalence of genital chlamydia infection in males using enzyme immunoassay of urinary sediment				
Start Date: May 92	Est. Compl. Date:				
Principal Investigator(s): Thomas P. Garigan, CPT, MC	Facility: Eisenhower Army Medical Center				
Department/Service: Family Practice	Associate Investigators: Eugenia Walsh, CPT, MC David P. Goldman, CPT, MC				
Key Words:					
Accumulative MEDCASE Cost:	Periodic Review Results:				

Study Objective: To establish protocols for study of the epidemiology of urogenital chlamydia infections.

Technical Approach: Epidemiologic

Number of subjects enrolled to date: 97

Progress: 97 male members of a new AIT class were given a questionnaire and submitted a urine sample which was centrifuged. The sediment was tested by enzyme immunoassay for chlamydia. Of the 97 subjects, 88 returned surveys, of which 5 indicated genital symptoms and/or dysuria. All 97 urine samples were tested twice and none were positive for chlamydia. The results of this initial study have not been summarized as the associate investigator is awaiting correspondence from the principal investigator.

DETAIL SUMMARY SHEET

Date:	13 Oct 92	Protocol #:	78-38	Status:	Terminated
Title:	Efficacy of immunotherapy for systemic allergic reaction to imported fire ant stings. Human immunologic reactivity to fire ant antigens. BB IND 1452, Part III				
Start Date:	Feb 78	Est. Compl. Date:			
Principal Investigator(s):	Angelina J. LePage, MAJ, MC		Facility:	Eisenhower Army Medical Center	
Department/Service:	Medicine/Allergy		Associate Investigators:	Robert B. Rhoades, MD Chester T. Stafford, MD Medical College of Georgia	
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective: a. To ascertain the relative efficacy of immunotherapy with whole body extracts and venom compared to placebo in the treatment of systemic hypersensitivity to stings of the imported fire ant.

b. To ascertain the natural history of imported fire ant hypersensitivity and to identify possible subgroups who may undergo spontaneous desensitization and not require immunotherapy.

Technical Approach: Experimental design: Patients found to be allergic to fire ants by history and laboratory parameters will be placed on placebo, whole body extract or venom. After approximately eight weeks, patients will be hospitalized for repeat laboratory parameters and challenge to fire ant bite. Depending on outcome, adjustment of treatment will be done accordingly.

Number of subjects enrolled to date: 7

Number of subjects enrolled for reporting period: 0

Progress: Protocol is deactivated due to inability to enroll patients at DDEAMC. Dr. Stafford is continuing the study at MCG under his own IND.

DETAIL SUMMARY SHEET

Date:	17 Jun 92	Protocol #:	88-24	Status:	Terminated
Title:	Pathophysiology of coronary artery dilatation				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):			Facility:		
George S. Rebecca, COL, MC			Eisenhower Army Medical Center		
Department/Service:			Associate Investigators:		
Medicine/Cardiology					
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective: To attempt to confirm that the normal response to increased coronary blood flow is endothelium-dependent epicardial artery dilation and that in atherosclerosis this important endothelial function is not lost.

Technical Approach: We plan to study adult male and female patients ages 18 to 75 years who present with chest pain, a stable clinical course and suitable coronary anatomy at diagnostic catheterization.

Number of subjects enrolled to date: 10

Number of subjects enrolled for reporting period: 0

Progress: PI has left the service. Terminate.

DETAIL SUMMARY SHEET

Date:	20 Oct 92	Protocol #:	89-40	Status:	Completed
Title:	An open protocol for the use of Agrelin (Anagrelide) for patients with thrombocythemia				
Start Date:	May 90	Est. Compl. Date:			
Principal Investigator(s):	Mark R. Keaton, MAJ, MC		Facility:	Eisenhower Army Medical Center	
Department/Service:	Medicine/Oncology		Associate Investigators:		
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Compassionate treatment protocol.

Total number of subjects enrolled: 4

Number enrolled this year: 0

Progress: Study closed by company.

DETAIL SUMMARY SHEET

Date: 16 Jun 92		Protocol #: 90-12		Status: Terminated	
Title: Coronary reactivity in response to nitrous oxide inhalation					
Start Date:			Est. Compl. Date:		
Principal Investigator(s): George S. Rebecca, COL, MC			Facility: Eisenhower Army Medical Center		
Department/Service: Medicine/Cardiology			Associate Investigators: Michael Goldfinger, CPT, MC		
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective: To study patients with various degrees of coronary artery disease or normal coronary arteries to evaluate the coronary diameter and flow character in response to nitrous oxide.

Progress: PI has left the service. Terminate.

DETAIL SUMMARY SHEET

Date:	21 Oct 92	Protocol #:	90-16	Status:	Ongoing
Title:	Study of Vespa fire ant venom in the diagnosis of fire ant reactivity				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	Angelina J. LePage, MAJ, MC		Facility:	Eisenhower Army Medical Center	
Department/Service:	Medicine/Allergy		Associate Investigators:	Chester Stafford, MD, MCG Michael O'Connell, MAJ, MC	
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective: To compare skin test reactivity of Vespa fire ant venom to that of two commercially available IFA whole body extract preparations.

Number of subjects enrolled to date: 28

Number enrolled for reporting period:

Progress: Study ongoing.

DETAIL SUMMARY SHEET

Date:	20 Apr 92	Protocol #:	90-24	Status:	Completed
Title:	Metabolic factors influencing myocardial recovery from acidosis				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	Richard F. Kucera, MAJ, MC		Facility:	Eisenhower Army Medical Center	
Department/Service:	Medicine/Pulmonary		Associate Investigators:	Joseph I. Shapiro, MD Laurence Chan, MD, PhD Univ of Colorado Jesse Doers, MAJ, MC	
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective: To determine the metabolic mechanisms by which cardiac function is depressed during severe acidosis and the pharmacologic maneuvers by which functional recovery may be enhanced or accelerated.

Funding: A total of \$41,750 was provided this fiscal year by MRDC.

Progress: The mechanisms involved in cardiac dysfunction during acidosis were explored in an isolated heart model. Metabolic acidosis was observed to cause marked functional and energy metabolic derangements consistent with a primary impairment of energy production. Synergism with hypoxia was also demonstrated in this model. The site of metabolic blockade during acidosis was observed to be at the level of oxidative metabolism and not glycolysis. Isolated cardiac mitochondrial studies, however, did not demonstrate any direct effect of acidosis on mitochondrial respiration or coupling. Studies with respiratory acidosis were complicated by the coexistence of relative hypoxia which affected the model deleteriously. Treatment of acidotic isolated hearts with the experimental buffer, Carbicarb, caused marked increases in intracellular Ph as well as functional and metabolic improvements. Isotonic rather than hypertonic Carbicarb was found to be substantially more effective in this model. The superiority of isotonic to hypertonic Carbicarb may be related to the tendency of hypertonic but not isotonic Carbicarb to significantly increase cytosolic sodium concentrations.

Mechanism of impaired energy metabolism during acidosis role of oxidative metabolism. Am J Physiol. In Press.

Hypoxia and metabolic acidosis in the isolated heart: Evidence for synergistic injury. Magn Reson Med. In Press.

Presented at the Western Soc Clin Res 1992.

DETAIL SUMMARY SHEET

Date:	31 Mar 92	Protocol #:	90-27	Status:	Terminated
Title:	Diurnal changes in coronary artery vasodilating properties				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	George S. Rebecca, COL, MC		Facility:	Eisenhower Army Medical Center	
Department/Service:	Medicine/Cardiology		Associate Investigators:	Anthony Chappell, CPT, MC	
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective: To evaluate the coronary diameter and flow characteristics in response to stress of a mental arithmetic problem and infusions of adenosine and acetylcholine.

Progress: PI left the service, terminate.

DETAIL SUMMARY SHEET

Date:	14 Jan 92	Protocol #:	91-1	Status:	Completed
Title:	A treatment IND protocol for the use of VIDEX (2',3'-Dideoxyinosine, ddl) in patients with AIDS or AIDS related complex who are intolerant to zidovudine				
Start Date:	3 Dec 91	Est. Compl. Date:			
Principal Investigator(s):	Jeffrey L. Lennox, MAJ, MC		Facility: Eisenhower Army Medical Center		
Department/Service:	Medicine/Infectious Disease		Associate Investigators:		
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective: To make ddl available to HIV infected patients who are: 1) either unable to tolerate zidovudine or deteriorating on zidovudine; and 2) unable to enter the Phase II ddl protocol due to geographic location.

Technical Approach: This is an open label drug protocol. No control group is included. Patients are administered ddl daily and followed for adverse reactions. No additional manpower or funding is required. No significant adverse reactions have been observed.

Total number of subjects enrolled to date: 3

Number of subjects enrolled for the reporting period: 0

Progress: Drug approved for marketing by FDA.

DETAIL SUMMARY SHEET

Date:	2 Oct 92	Protocol #:	91-14	Status:	Ongoing
Title:	Comparison of intravenous H-2 antagonists and their influence on gastric emptying on insulin dependent diabetics				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	Eugene Ryan, CPT, MC		Facility:	Eisenhower Army Medical Center	
Department/Service:	Medicine		Associate Investigators:	Carl P. Stamm, LTC, MC Stephen G. Oswald, LTC, MC	
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective: To study the effect of a single standard IV dose of famotidine, cimetidine and ranitidine on GE in adult diabetics.

Technical Approach: Each patient will be studied in the fasting state on four different days spaced at least 72 hours apart. Prior to each gastric emptying study the subjects will receive an IV bolus injection of either one of cimetidine, ranitidine, famotidine, or placebo.

Number of subjects enrolled for the reporting period: 2

Progress: Study ongoing.

DETAIL SUMMARY SHEET

Date:	21 Oct 92	Protocol #:	91-15	Status:	Ongoing
Title:	Epidemiology <i>Clostridium difficile</i> infections and diarrhea in a population of military HIV patients				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	David R. Haburchak, COL, MC		Facility:	Eisenhower Army Medical Center	
Department/Service:	Medicine		Associate Investigators:	David W. Craft, MAJ, MS Donald E. Sutherland, MAJ, MS Jeffrey L. Lennox, MAJ, MC	
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective: To determine the epidemiology of *Clostridium difficile* infections on Ward 11E in HIV and mixed internal medicine patient ward and appropriate measures for infection control.

Technical Approach: A prospective study of all patients admitted to Ward 11E will be conducted for the incidence and prevalence of *C. difficile* stool culture positivity and clinical disease. After two months, an educational intervention program will be conducted with followup results determined.

Progress: Study on hold until administrative problems are worked out.

DETAIL SUMMARY SHEET

Date:	21 Oct 92	Protocol #:	92-1	Status:	Ongoing
Title:	Serologic survey of active duty dependent and retired military population for evidence of <i>helicobacter pylori</i> (<i>Campylobacter pylori</i>) infection at a US Army Medical Treatment Facility				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	David R. Haburchak, COL, MC		Facility:	Eisenhower Army Medical Center	
Department/Service:	Medicine		Associate Investigators:	David W. Craft, PhD, MAJ, MS Donald E. Sutherland, PhD, MAJ, MS Norma Best, MT	
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective: What is the prevalence of *H. pylori* associated infection in a military population including gastroenterology patients? What is the efficacy of triple therapy in a nonselected population of seropositive patients?

Technical Approach: A simplified nonblinded treatment protocol will be instituted based on the knowledge of the role of *Helicobacter* in association with gastritis and peptic ulcer disease in the literature, its responsiveness to therapy and the ethics of withholding potentially curative therapy. This study will simulate clinical practical use of this modality of treatment/management for its practicality and ease.

Subjects enrolled to date: 22

Progress: Patient enrollment and data collection continues.

DETAIL SUMMARY SHEET

Date:	8 Oct 92	Protocol #:	92-10	Status:	Ongoing
Title:	A comparison of the efficacy, safety, and tolerance of ceftibuten (SCH 39720) 300 mg given BID and augmentin 500 mg given TID in the treatment of community acquired pneumonia				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	Warren L. Whitlock, LTC, MC		Facility:	Eisenhower Army Medical Center	
Department/Service:	Medicine/Pulmonary		Associate Investigators:	Wayne T. Honeycutt, MAJ, MC Jesse J. Doers, MAJ, MC	
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective: To compare the efficacy, safety, and tolerance of high-dose ceftibuten (SCH 39720) 300 mg BID with that of augmentin 500 mg TID in the treatment of pneumonia in adults.

Technical Approach: Treatment will follow outline in Schering-Plough protocol.

Subjects enrolled to date: 5

Progress: Enrollment of subjects has been slower than anticipated due to the summer season. We have given in-services for the Departments of Medicine, Family Practice, Emergency, Respiratory Therapy, and TMC 1, 2, & 4. We have had no serious complications and anticipate finishing the study well before the deadline.

DETAIL SUMMARY SHEET

Date:	26 Jun 92	Protocol #:	92-2	Status:	Withdrawn
Title:	Safety and efficacy of amphotericin B lipid complex in the treatment of cryptococcal meningitis in patients with acquired immunodeficiency syndrome				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	Jonathan D. Berman, COL, MC		Facility:	Eisenhower Army Medical Center	
Department/Service:	Medicine		Associate Investigators:	Daniel B. Craig, COL, MC	
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Withdrawn per PI.

DETAIL SUMMARY SHEET

Date:	8 Oct 92	Protocol #:	92-9	Status:	Ongoing
Title:	A comparison of the efficacy, safety, and tolerance of ceftibuten (SCH 39720) 400 mg (1 x 400 mg capsule) in the fed and fasted state and augmentin amoxicillin/clavulanate 1.5 gm (1 x 500 mg tablet TIC) in the fed state in the treatment of acute exacerbations of chronic bronchitis				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	Warren L. Whitlock, LTC, MC		Facility:	Eisenhower Army Medical Center	
Department/Service:	Medicine/Pulmonary		Associate Investigators:	Wayne T. Honeycutt, MAJ, MC Jesse J. Dcers, MAJ, MC	
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective: To compare the efficacy, safety, and primarily, the GI tolerance of once-daily Cedax ceftibuten (SCH 39720) in both the fed and fasted state with that of Augmentin amoxicillin/clavulanate given TID int he fed state in the treatment of acute exacerbations of chronic bronchitis in adults.

Technical Approach: Treatment will follow outline in Schering-Plough protocol.

Subjects enrolled to date: 6

Progress: Enrollment of subjects has been slower than anticipated due to the summer season. In-services provided to the Departments of Medicine, Family Practice, Emergency, Respiratory Therapy, and TMC 1, 2, & 4. There have been no serious complications and anticipate finishing the study well before the deadline.

DETAIL SUMMARY SHEET

Date:	27 Oct 92	Protocol #:	92-18	Status:	Ongoing
Title:	Prediction of endogenous erythropoietin levels from the hematocrit and serum creatinine				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	Bobby W. Jones, CPT, MC		Facility:	Eisenhower Army Medical Center	
Department/Service:	Medicine/Hematol-Oncol, Nephrology/Family Practice		Associate Investigators:	Patrick W. Cobb, MAJ, MC John W. Nolan, MAJ, MC Amy W. Sprague, MAJ, MC	
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective: To determine if the clinician can use values obtained from routine laboratory studies solely and appropriately in medical decision making with reference to exogenous erythropoietin therapy.

Technical Approach:

Subjects enrolled to date:

Progress: No reportable data.

DETAIL SUMMARY SHEET

Date:	27 Oct 92	Protocol #:	92-20	Status:	Completed
Title:	Compassionate use of protocol 102-012 - An open study of teicoplanin in the treatment of acute bone and joint infections caused by gram positive bacteria				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	Craig E. Smith, MAJ, MC		Facility:	Eisenhower Army Medical Center	
Department/Service:	Medicine/Infectious Disease		Associate Investigators:		
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective: Emergency use.

Progress: This was a single patient emergency use protocol. The patient received 8 weeks of drug therapy without side effects or complications. She has apparently been cured although she is still being followed as an outpatient.

DETAIL SUMMARY SHEET

Date:	8 Oct 92	Protocol #:	92-22	Status:	Terminated
Title:	Correlation of conventional angiography to magnetic resonance angiography				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	Robert Morgan, CPT, MC		Facility:	Eisenhower Army Medical Center	
Department/Service:	Medicine/Surgery/Radiology		Associate Investigators:	Jerry Allison, M.D. Thomas Ralston, LTC, MC Manuel Ramirez, LTC, MC Stephen Flaherty, CPT, MC	
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective:

Technical Approach:

Subjects enrolled to date:

Progress: PI PCS'd Jun 92, no report submitted, terminate.

DETAIL SUMMARY SHEET

Date:	8 Oct 92	Protocol #:	92-25	Status:	Terminated
Title:	A multicenter double-blind, randomized, comparative study of the efficacy and safety of intravenous temafloxacin <i>versus</i> intravenous imipenem-cilastatin sodium in the treatment of nosocomial pneumonia				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	Warren L. Whitlock, LTC, MC		Facility:	Eisenhower Army Medical Center	
Department/Service:	Medicine/Pulmonary Disease		Associate Investigators:	Wayne L. Honeycutt, MAJ, MC Jesse Doers, MAJ, MC	
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective: To compare the efficacy and safety of intravenous temafloxacin with that of intravenous imipenem-cilastatin sodium in the treatment of patients with nosocomial pneumonia.

Technical Approach: Treatment will follow outline in Abbott Laboratories' protocol.

Number of subjects enrolled: 1

Progress: This was a very promising study which unfortunately was terminated by the pharmaceutical company secondary to adverse side effects reported with the oral form of the drug. At the time of termination of this protocol, we only had one patient enrolled. This patient did well and had no adverse side effects to the drug. Abbott has already gathered all the necessary information ont his patient and the results of the study are maintained by our clinical coordinator.

DETAIL SUMMARY SHEET

Date:	6 Oct 92	Protocol #:	92-30	Status:	Ongoing
Title:	Techniques of use of metered dose inhalers				
Start Date: Apr 92			Est. Compl. Date:	June 93	
Principal Investigator(s): Richard B. Hilburn, CPT, MC			Facility: Eisenhower Army Medical Center		
Department/Service: Medicine/Pulmonary Disease			Associate Investigators: Warren L. Whitlock, MAJ, MC Jesse T. Doers, MAJ, MC Ray Scarlett, CRT		
Key Words: MDI, Metered dose inhalers					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective: To evaluate the techniques of use of MDI by the EAMC patient population. To determine which of 3 teaching modalities is the most effective in improving technique. To detect any implication of impact of improved technique upon emergency room visits and hospitalizations for the study population.

Subjects enrolled to date: 43

Progress: Composition of patient packets per each of 4 groups. Videotaping of instructional program for group 3. Initiation of patient population 9/92, has just begun. Additional patient packets printing request submitted to newly reopened printing support section, DDEAMC. No funding support requested.

DETAIL SUMMARY SHEET

Date:	21 Oct 92	Protocol #:	92-35	Status:	Terminate
Title:	Open label trial of centoxin (HA-1A) treatment of presumed gram-negative sepsis				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	Wayne T. Honeycutt, MAJ, MC		Facility:	Eisenhower Army Medical Center	
Department/Service:	Medicine/Pulmonary Disease		Associate Investigators:		
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective: One time emergency use of an investigational drug.

Progress: Terminate, patient died.

DETAIL SUMMARY SHEET

Date:	7 Oct 92	Protocol #:	92-47	Status:	Ongoing
Title:	A double-blind, placebo controlled, parallel group, multicenter study of the use of weekly azithromycin as prophylaxis against the development of <i>Mycobacterium avium complex</i> disease in HIV infected people				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	Daniel B. Craig, COL, MC		Facility:	Eisenhower Army Medical Center	
Department/Service:	Medicine/Infectious Disease		Associate Investigators:	Craig E. Smith, MAJ, MC David R. Haburchak, COL, MC	
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective: To evaluate the safety and efficacy of azithromycin administered once a week in the prevention of disseminated MAC in severely immunocompromised HIV infected patients with a CD4 count < 100/ul.

Technical Approach: Treatment will follow outline per Pfizer protocol.

Subjects enrolled to date: 0

Progress: Awaiting HSC approval to begin enrolling patients.

DETAIL SUMMARY SHEET

Date:	21 Oct 92	Protocol #:	92-60	Status:	Ongoing
Title:	A double-blind randomized parallel study of the antiemetic effectiveness of IV Dolasetron mesylate VS IV Zofran in patients receiving cisplatin chemotherapy				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	Mark R. Keaton, MAJ, MC		Facility:	Eisenhower Army Medical Center	
Department/Service:	Medicine/Oncology		Associate Investigators:	Richard S. Foulke, MAJ, MC Don Shaffer, MAJ, MC Robert Krywicki, MAJ, MC	
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective: To establish efficacy by showing that there is a trend toward decreased emesis following cisplatin (≥ 70 mg/m²) with increasing doses of dolasetron mesylate. To evaluate the dose-response relationship across 0.6, 1.2, 1.8, 2.4, and 3.0 mg/kg single intravenous (IV) doses of dolasetron mesylate in preventing emesis due to cisplatin (≥ 70 mg/m²) chemotherapy. To evaluate the safety and tolerance of dolasetron mesylate when given for this indication. To characterize the population pharmacokinetic and pharmacodynamic models of dolasetron mesylate and/or its metabolite(s) and their interindividual variabilities in patients receiving cisplatin. To compare the degree of patient satisfaction among the antiemetic dose levels.

Technical Approach: This is a five arm, double-blind, randomized, dose response study in which patients with a history of histologically confirmed malignant disease will receive a single dose of dolasetron mesylate. Patients of either sex and any race will be admitted to this study. They must be undergoing their first course of cisplatin-containing chemotherapy. The cisplatin dose will be ≥ 70 mg/m² and infused over no more than 3 hours as the first component of a chemotherapy regimen.

Number of subjects enrolled to date: 0

Progress: Plan to start enrolling patients in October. Awaiting HSC approval.

DETAIL SUMMARY SHEET

Date:	21 Oct 92	Protocol #:	92-61	Status:	Ongoing
Title:	A five arm double-blind randomized dose-response study of the antiemetic effectiveness of IV Dolasetron mesylate in patients receiving cisplatin chemotherapy				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	Mark R. Keaton, MAJ, MC		Facility:	Eisenhower Army Medical Center	
Department/Service:	Medicine/Oncology		Associate Investigators:	Richard S. Fowler, MAJ, MC Don Shaffer, MAJ, MC Robert Krywicki, MAJ, MC	
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective: To determine the relative effectiveness of a single 2.4 mg/kg intravenous (IV) dose of dolasetron mesylate versus the approved dose regimen of ondansetron (0.15 mg/kg Qh4 x3) for complete prevention of emesis due to ≥ 70 mg/m² of cisplatin chemotherapy. To evaluate the safety and tolerance of dolasetron mesylate versus ondansetron when given for this indication. To compare patient satisfaction with the two antiemetic agents.

Technical Approach: This is a double-blind, randomized, parallel study in which patients with a history of histologically confirmed malignant disease will receive either IV dolasetron mesylate (2.4 mg/kg) or IV ondansetron (3 x 0.15 mg/kg). The cisplatin dose will be ≥ 70 mg/m² and infused over no more than 3 hours as the first component of a chemotherapy regimen.

Number of subjects enrolled to date: 0

Progress: Plan to start enrolling patients in October. Presently awaiting HSC approval.

DETAIL SUMMARY SHEET

Date:	8 Oct 92	Protocol #:	92-67	Status:	Ongoing
Title:	Evaluation of the Use of ^{99m} Technetium Pertechnetate with Potassium Perchlorate Wash-out and ^{99m} Technetium MIBI in Parathyroid Imaging in Patients with Suspected Parathyroid Neoplasia or Hyperplasia				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	Rama G. Eachempati, MD, LTC, MC		Facility:	Eisenhower Army Medical Center	
Department/Service:	Medicine/Infectious Disease		Associate Investigators:		
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective:

Technical Approach:

Progress: Local approval late FY 92, no progress to report.

DETAIL SUMMARY SHEET

Date:	8 Oct 92	Protocol #:	92-73	Status:	Ongoing
Title:	Comparative Study of Liver Biopsies and Quantitative Hepatobiliary Scanning in Patients with Hepatitis C				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):			Facility:		
Anwar K. Malik, MD, MAJ, MC			Eisenhower Army Medical Center		
Department/Service:			Associate Investigators:		
Medicine					
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective: To determine if quantified hepatobiliary scan with 99Tc-IDA could be substituted for liver biopsy in patients with Hepatitis C.

Technical Approach:

Number of subjects enrolled to date:

Progress: Local approval late FY 92, no progress to report.

DETAIL SUMMARY SHEET

Date:	8 Oct 92	Protocol #:	92-78	Status:	Ongoing
Title:	A Multicenter, Open Label, Pilot Study of Axithromycin in the Outpatient Treatment of Lower Respiratory Tract Infection Due to Atypical Respiratory Pathogens				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	Warren L. Whitlock, MD, LTC, MC		Facility:	Eisenhower Army Medical Center	
Department/Service:	Medicine/Pulmonary		Associate Investigators:		
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective: To investigate azithromycin in the treatment of lower respiratory tract infections due to the atypical respiratory pathogens *C. pneumoniae*, *M. pneumoniae* and *L. pneumophila*.

Technical Approach:

Number of subjects enrolled to date:

Progress: Local approval late FY 92, awaiting HSC approval.

DETAIL SUMMARY SHEET

Date:	20 Oct 92	Protocol #:	91-11	Status:	Completed
Title:	A study of the relation of personality, context, level of distress, and coping process, in Army Reserve Nurses mobilized in Operation Desert Shield				
Start Date:	Oct 90	Est. Compl. Date:			
Principal Investigator(s):	Lorraine Braswell, LTC, AN		Facility: Eisenhower Army Medical Center		
Department/Service:	Nursing		Associate Investigators:		
Key Words:	Coping-emotion, Problem focused, Mobilization				
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective: To study the effects of mobilization on Army Reserve nurses as it relates to an individual's personality and situation. To determine how and if the above variables influence coping.

Technical Approach: A demographic questionnaire was mailed to 160 nurse officers, a coping questionnaire, and a measure of affect - 50% response.

Progress: Completed.

DETAIL SUMMARY SHEET

Date:	8 Oct 92	Protocol #:	92-72	Status:	Ongoing
Title:	Experiences of Couples Participating in a Counseling Program to Abate Spouse Abuse: A Descriptive Clinical Report				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	Dorothy A. Anderson, MAJ, AN		Facility:	Eisenhower Army Medical Center	
Department/Service:	Nursing		Associate Investigators:		
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective:

Technical Approach:

Progress: Local approval late FY 92, no progress to report.

DETAIL SUMMARY SHEET

Date:	20 Oct 92	Protocol #:	91-44	Status:	Completed
Title:	Dental liquid ration evaluation protocol				
Start Date:	Aug 91	Est. Compl. Date:			
Principal Investigator(s):	Facility:				
Diana J. Smith, CPT, SP	Eisenhower Army Medical Center				
Department/Service:	Associate Investigators:				
Nutrition Care Division	Simone D. Adams Denise Y. Chandler, SFC				
Key Words:					
Accumulative MEDCASE Cost:	Periodic Review Results:				

Study Objective: To determine the acceptance and nutritional adequacy of the twenty new dental liquid products when compared to the current hospital liquid diet.

Technical Approach: Diet will be provided to special candidates on a rotating basis according to a predesigned calendar. Our original advanced liquid diet will alternate with the prepackaged diet and patient will answer appropriate questionnaire. Project funded by OTSG.

Number of subjects enrolled for reporting period: 1

Progress: Study completed.

DETAIL SUMMARY SHEET

Date:	6 Oct 92	Protocol #:	89-29	Status	Terminate
Title:	Use of the Vira pap to plan therapy for HPV associated lesions of the cervix				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	John W. Spurlock, CPT, MC		Facility:	Eisenhower Army Medical Center	
Department/Service:	Obstetrics-Gynecology, Clinical Investigation, Pathology		Associate Investigators		
Key Words:			Terrel Michel, COL, MC Gary B. Broadnax, COL, MC Tu H. Nguyen, LTC, MC David K. Turgeon, CPT, MS		
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective: To determine the prevalence of HPV in our active duty female population. To identify the strain of HPV in patients with an abnormal Pap smear.

Technical Approach: Population will be a random sample of routine GYN patients coming in for a Pap smear. A Pap smear and Vira pap will be done on these patients. If both tests are negative they will receive routine followup. If the Pap smear and/or the Vira pap is positive they will have a colposcopy done. If the colposcopy records only warty changes and the strain is 6 or 11, they will be randomized into a treat vs non-treatment group. The treatment group will have laser vaporization of the cervix. The non-treatment group will be followed with Pap smear/colposcopy every 3-4 months. If the colposcopy or the strain of virus is of a high risk group (16, 18, 31) they will all be treated with laser ablation.

Number of subjects enrolled to date: 4

Number of subjects enrolled for reporting period:

Progress: Both investigators have left, terminate study per department chief.

DETAIL SUMMARY SHEET

Date:	9 Oct 92	Protocol #:	91-20	Status:	Completed
Title:	To determine the effect of age and exercise on plate function				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	Rowland E. Ochia, LTC, MC		Facility:	Eisenhower Army Medical Center	
Department/Service:	Pathology		Associate Investigators:	Isaac D. Broussard, MAJ, MC	
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective: To test if platelets from different age groups are equally functional as far as platelet transfusion into those patients who are refractory to platelet therapy.

Technical Approach: To test the function of platelets (aggregation) in subjects under 25 years of age and compare it to those from subjects over 25 years.

Progress: All samples from both age groups were treated and handled the same way. Review of all the tracings failed to show any difference in aggregation function of the platelets from different age groups.

DETAIL SUMMARY SHEET

Date:	13 Oct 92	Protocol #:	87-45	Status:	Completed
Title:	Child Psychiatric Data Base Project				
Start Date:	Jul 87	Est. Compl. Date:			
Principal Investigator(s):	Facility:				
Peter S. Jensen, MAJ, MC	Eisenhower Army Medical Center				
Department/Service:	Associate Investigators:				
Psychiatry & Neurology, Social Work Service	Dan O'Brien, LTC, MS Ms Marilyn Reedy Earl Loomis, MD, MCG Alex Mabe, PhD, MCG Robert C. Ness, PhD, MCG Harry Davis, M.S., MCG R. Adair Blackwood, MD, Charter Joseph Frey, PhD, MCG				
Key Words:					
Accumulative MEDCASE Cost:	Periodic Review Results:				

Study Objective: To facilitate the development of a collaborative data base and computer scoring system of data items completed by parents or the child's main caretaking figures.

Technical Approach: The 94-item data instrument is presently in use in our routine child psychiatric evaluative settings.

Number of subjects enrolled to date: 600

Number of subjects enrolled for reporting period:

Progress: Study completed, all investigators have left the area.

DETAIL SUMMARY SHEET

Date:	21 Oct 92	Protocol #:	90-34	Status:	Completed
Title:	The demographics of patients with late luteal phase dysphoric disorder as seen in a military care setting				
Start Date:	Sep 90	Est. Compl. Date:			
Principal Investigator(s):	David Schenk, CPT, MC		Facility: Eisenhower Army Medical Center		
Department/Service:	Psychiatry & Neurology		Associate Investigators: James Reed, MAJ, MC James Williford, CPT, MC Charles Perrotta, CPT, MC		
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective: To evaluate the demographics of a population with late luteal phase dysphoric disorder as seen in a military setting. The implications of this data on care in the military system will be explored.

Technical Approach: The study involves several questionnaires and venipuncture in conjunction with a physical examination.

Total number of subjects enrolled to date: 22

Progress: Subjects completed this study and were enrolled in 91-17.

DETAIL SUMMARY SHEET

Date:	19 Jun 92	Protocol #:	91-17	Status:	Completed
Title:	The efficacy of fluoxetine <i>versus</i> placebo in the treatment of late luteal phase dysphoric disorder				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	David Schenk, CPT, MC		Facility:	Eisenhower Army Medical Center	
Department/Service:	Psychiatry & Neurology		Associate Investigators:	James Reed, MAJ, MC James Williford, CPT, MC Charles Perrotta, CPT, MC	
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective: Patients will be referred from a previous protocol designed to delineate the demographics of patients with LLPDD seen at DDEAMC. All patients referred into this protocol will have completed medical and laboratory evaluation as per attached protocol and will have met the criteria for LLPDD as defined in the DSM III Revised to include prospective ratings for a two month period.

Total number of subjects enrolled to date: 6

Progress: Results of the study suggest that fluoxetine is more effective than placebo in the treatment of LLPDD. Considering that fluoxetine is relatively specific for serotonin reuptake inhibition, the results of this study, in addition to other recent pilot studies with serotonergic agents, may implicate a role for serotonin in the etiology of LLPDD. Further controlled studies of longer duration and larger sample sizes are indicated to confirm the effectiveness of fluoxetine in the treatment of LLPDD. Also, a controlled study comparing fluoxetine to a drug that is more specifically noradrenergic would help elucidate specific roles of serotonin versus norepinephrine

DETAIL SUMMARY SHEET

Date:	22 Jun 92	Protocol #:	91-60	Status:	Completed
Title:	The incidence and prevalence of psychiatric diagnoses in military personnel medically evacuated from Operation Desert Storm to a major medical center				
Start Date:	May 91	Est. Compl. Date:			
Principal Investigator(s):	Charles Perrotta, Jr., CPT, MC		Facility: Eisenhower Army Medical Center		
Department/Service:	Psychiatry & Neurology		Associate Investigators: Carolyn Randle, LTC, MC		
Key Words:					
Accumulative MEDCASE Cost:	Periodic Review Results:				

Study Objective: To determine the incidence and prevalence of psychiatric diagnosis in medically evacuated casualties from Operation Desert Storm. Also, to compare the incidence and prevalence of psychiatric diagnosis in full-time military personnel vs reserve personnel.

Technical Approach: Medically evacuated casualties will be evaluated by a psychiatric consultation/liaison team representative who will obtain a psychiatric history and will also conduct a mental status examination.

Number of subjects enrolled to date: 105

Number of subjects enrolled for the reporting period: 0

Progress: One hundred and seventy-seven patients were evacuated to DDEAMC between February 11, 1991 and May 16, 1991. Representatives of a psychiatric consultation team were able to conduct diagnostic evaluations on 105 soldiers, to include psychiatric history and mental status examination. Diagnoses were determined according to DSM-III-R criteria. Sixteen patients were determined to have active Axis I diagnoses in addition to their medical diagnoses. Of the 105 interviewed 53 were Reserve or National Guard and 50 were full-time military. The data demonstrates that many of the medical and/or surgical evacuees who were not given psychiatric diagnoses at the time of evacuation had significant Axis I disorders when evaluated by trained psychiatric personnel. A greater percentage of reservists (11 of 53 or 20.8%) than full-time military active duty (5 of 50 or 10%) were among those patients with current Axis I diagnoses. Also, a greater percentage (13 of 78 or 16.7%) of patients with non-combat related injuries and/or illness than patients with combat related injuries (3 of 27 or 11.1%) were among those with current Axis I diagnoses. In addition to the above, our data suggests that psychiatric evaluation during evacuation may uncover patients with a higher potential for disturbed adaptation post-war (the V codes, for example, and the alcohol abuse diagnoses). Whether or not a psychiatric diagnosis was given, the data here suggests that many of the medical and surgical patients evacuated from Operation Desert Storm to DDEAMC had conditions that might benefit from psychiatric and/or some other form of supportive intervention. Perhaps proper intervention can make the difference between mental health and maladjustment. If we assume this to be true then it

seems reasonable to suggest that in future conflicts the first step toward proper intervention is to recognize that a potential problem exists. It is our hope that the current study provides some indications of the need for psychiatric evaluation and care in medical and surgical patients evacuated from a large military operation.

DETAIL SUMMARY SHEET

Date:	22 Jun 92	Protocol #:	91-71	Status:	Completed
Title:	A study of the prevalence of dissociative disorder in alcohol and drug abusing population in a military residential treatment facility and changes in the incidence resulting from treatment and abstinence while in the treatment program				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	David H. Leeper, LTC, MC		Facility:	Eisenhower Army Medical Center	
Department/Service:	Psychiatry & Neurology		Associate Investigators:	Ben Page, LTC, MC Daniel Hendricks, PhD	
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective: The repeat testing of the subjects five weeks into a six week program is to determine if the incidence/report of dissociative experience in the patient population changes with sobriety and treatment in the RTF. There may be implications for later study to see if the recognition/diagnosis of dissociative disorder may later be linked to success or failure of the individual in treatment.

Technical Approach: Every fifth patient for the study will not be evaluated by the test instruments until week five. The other four members of the class will receive the DES on admission and the DDIS. During week five, they will be given the DES and DDIS repeat.

Number of subjects enrolled: 78

Progress: Seventy-eight patients were interviewed over a six month period utilizing the DDIS and the DES to examine the prevalence of dissociative disorders and changes in prevalence during the six week treatment program. Twelve (12.8%) endorsed a dissociative disorder on the DDIS and 24 (30.7%) had a DES score of 20 or more, with ten (12.8%) having a DES score of 30 or more. No significant changes were noted as a result of the second evaluation. No diagnosis of dissociative disorder was found on review of admission and discharge record. The prevalence of dissociative disorder in this population is lower than in other studies published in the last few years. This may be related to the demographics of the particular population. This study replicates other studies in that the DES scores are relatively enduring over time and are unrelated to cognitive changes or treatment. Secondly, the diagnosis of dissociative disorder is under-reported in this population of chemically abusing individuals.

DETAIL SUMMARY SHEET

Date:	5 Oct 92	Protocol #:	92-23	Status:	Ongoing
Title:	Determinants in the development of insight for substance dependence in rehabilitation facility inpatients				
Start Date:	Feb 92	Est. Compl. Date:	Jan 93		
Principal Investigator(s):	James Spinelli, MAJ, MC		Facility:	Eisenhower Army Medical Center	
Department/Service:	Psychiatry & Neurology		Associate Investigators:	Robert Ness, PhD Daniel Hendricks, PhD	
Key Words:	Insight, Substance abuse, Substance dependence				
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective. To discern specific aspects of an Inpatient Rehabilitation Facility which are most closely associated with the development of patient insight into acceptance of the disease of substance dependence or abuse.

Technical Approach: Using a questionnaire, anonymously survey a number of substance abuse patients gauging their insight before and after enrolling in the RTF. Then, comparing that data with their feelings about specific aspects of the RTF, measure statistical significance to see if certain aspects of RTF are more closely associated with insight formation than others.

Subjects enrolled to date: 92

Progress: All questionnaires have been completed, data collated and calculations tabulated among twenty-two different variables. A meeting of investigators has been scheduled for 7 October 1992 to discuss notable significance and trends. Afterward an initial draft of the written report will be prepared.

DETAIL SUMMARY SHEET

Date:	27 Oct 92	Protocol #:	92-43	Status:	Ongoing
Title:	The first break psychosis study				
Start Date: Sep 92			Est. Compl. Date:	May 95	
Principal Investigator(s): Elaine Correnti, MAJ, MC			Facility:	Eisenhower Army Medical Center	
Department/Service: Psychiatry & Neurology			Associate Investigators:	Richard Borison, MD Manuel Casanova, MD Laura Davidson, PhD Bruce Diamond, MD Sahebarao P. Mohadik, MD Sukdeb Mukherjee, MD Thomas Ralston, LTC, MC Russell Scheffer, CPT, MC Neal Trent, MAJ, MC	
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective: To determine whether specific biological abnormalities previously found in chronic schizophrenic patients are present at the beginning of the illness and, if so, to examine their relations to clinical characteristics of the illness; and to examine whether selected clinical, historical, and biological measures are predictive of short-term clinical outcome in patients experiencing their first episode of psychosis.

Technical Approach: Patients will undergo comprehensive psychiatric, neuropsychological, and neurological examinations at baseline, and blood samples will be taken for determination of RBC activities of specific enzymes and measurement of tritiated imipramine binding in platelets. A skin biopsy will be performed to develop fibroblast cell lines in culture and examine whether fibroblasts from patients show the abnormalities of growth and morphology noted in studies of chronic schizophrenic patients.

Subjects enrolled to date: 5

Progress: Five patients have undergone the initial baseline studies and are now engaged in weekly assessments as per the protocol.

DETAIL SUMMARY SHEET

Date:	21 Oct 92	Protocol #:	92-59	Status:	Ongoing
Title:	Monitoring of mood states in substance dependent subjects in inpatient rehabilitation facility				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	Patrick W. Clapper, CPT, MC		Facility:	Eisenhower Army Medical Center	
Department/Service:	Psychiatry & Neurology		Associate Investigators:	Daniel Hendricks, PhD	
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective:

Technical Approach:

Number of subjects enrolled to date:

Progress: No reportable data, late FY 92 local approval.

DETAIL SUMMARY SHEET

Date:	8 Oct 92	Protocol #:	92-42	Status:	Terminate
Title:	Development and validation of the Adlerian effective parenting inventory: A resolution to predicting the need and assessing the outcome of parent group education training				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	Tony Franklin, MAJ, MS		Facility:	Eisenhower Army Medical Center	
Department/Service:	Psychology		Associate Investigators:		
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective:

Technical Approach:

Subjects enrolled to date:

Progress: PI PCS'd Jul 92, did not submit report, terminate.

DETAIL SUMMARY SHEET

Date:	29 Sep 92	Protocol #:	90-1	Status:	Ongoing
Title:	Technitium 99m antimony trisulfide colloid for investigation of lymphatic drainage				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	Stephen G. Oswald, LTC, MC		Facility:	Eisenhower Army Medical Center	
Department/Service:	Radiology/Nuclear Medicine		Associate Investigators:		
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective: To provide a radiopharmaceutical whereby lymphatic drainage may be characterized.

Technical Approach: Intradermal injection of radiolabeled colloidal particles with serial gamma camera images to evaluate lymphatic drainage.

Number of subjects enrolled to date: 3

Progress: One additional patient enrolled during FY 92. No complications or adverse reactions noted. Protocol should remain open for possible additional entries.

DETAIL SUMMARY SHEET

Date:	9 Oct 92	Protocol #:	90-36	Status:	Ongoing
Title:	Treatment of internal contamination by plutonium and other transuranic elements with two investigational new drugs (Ca-DTPA and Zn-DTPA)				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	Robert J. Kaminski, LTC, MC		Facility:	Eisenhower Army Medical Center	
Department/Service:	Radiology/Nuclear Medicine		Associate Investigators:	Stephen G. Oswald, LTC, MC	
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective: The principal objective of this protocol is to obtain approval from the IRC to use Ca-DTPA and Zn-DTPA for the treatment of patients at Eisenhower Army Medical Center who are internally contaminated with plutonium or other transuranic elements.

This is not an investigational study, approval allows us to store the drugs in this facility.

DETAIL SUMMARY SHEET

Date:	2 Oct 92	Protocol #:	91-13	Status:	Ongoing
Title:	Scintigraphy of tumors of neuroectodermal origin with 131-iodine-meta-iodobenzylguanibine sulfate (131-I-MIBG)				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	Stephen G. Oswald, LTC, MC		Facility:	Eisenhower Army Medical Center	
Department/Service:	Radiology/Nuclear Medicine		Associate Investigators:	Robert J. Kaminski, LTC, MC James H. Corley, LTC, MC	
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective: To provide a mechanism whereby this agent is available for use in diagnostic studies in patients undergoing evaluation of pheochromocytoma or staging of neuroblastoma.

Technical Approach: Intravenous injection of a radiopharmaceutical (MIBG) with subsequent gamma camera imaging.

Number of subjects enrolled: 2

Progress: No adverse reactions. Study ongoing.

DETAIL SUMMARY SHEET

Date:	28 Sep 92	Protocol #:	91-38	Status:	Completed
Title:	Stability of technetium sulfur colloid labeled egg substitute in gastric acid: Comparison to <i>in vivo</i> labeled chicken liver				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	Stephen G. Oswald, LTC, MC		Facility:	Eisenhower Army Medical Center	
Department/Service:	Radiology/Nuclear Medicine		Associate Investigators:	Daryl S. Moyer, CPT, MS Julian Armstrong, MAJ, MC	
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective: To determine the *in vitro* stability of radiolabeled commercially available egg preparations in gastric juice. To compare this to the *in vitro* stability of the radiolabeled meal currently used at DDEAMC and to *in vivo* labeled chicken liver, a known standard.

Technical Approach: Each of the several commercially available egg substitutes, whole natural egg, and natural whole egg, and natural egg white will be labeled by injecting 1.0 mCi of technetium sulfur colloid into the egg during heat coagulation. An aliquot of each will be rinsed in normal saline and assayed. Additional samples will be placed in gastric juice, kept at 37° C, and periodically agitated. Samples will be removed from the gastric juice at 1 and 3 hours and rinsed with normal saline through a 1 mm wire mesh. The liquid and solid remnant will be assayed. All activity will be decay corrected to time zero. A single chicken will be anesthetized and injected into the wing vein with 3 Mci of Tc-SC. After 30 minutes the animal will be sacrificed and the liver removed. The liver will be rinsed, diced into 1 cm cubes, fried, and samples placed in gastric juice as above.

Progress: Study completed in Dec 91.

DETAIL SUMMARY SHEET

Date:	2 Oct 92	Protocol #:	91-39	Status:	Ongoing
Title:	Adrenal imaging with 131-iodine-6-beta-iodomethyl-norcholesterol (NP-59)				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	Stephen G. Oswald, LTC, MC		Facility:	Eisenhower Army Medical Center	
Department/Service:	Radiology/Nuclear Medicine		Associate Investigators:	Robert J. Kaminski, LTC, MC Daryl S. Moyer, CPT, MS	
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective: To provide a mechanism whereby NP-59 is available for correlative adrenal imaging for patients with biochemically established ACTH-independent Cushing's syndrome, primary aldosteronism, or androgen excess states as well as characterization of the functional status of euadrenal masses.

Technical Approach: Intravenous injection of a radiopharmaceutical (NP-59) with subsequent gamma camera imaging.

Progress: No patients enrolled. Study ongoing.

DETAIL SUMMARY SHEET

Date:	22 Jun 92	Protocol #:	90-13	Status:	Terminate
Title:	Long term evaluation of the effect of desipramine on cocaine use				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	Carolyn D. Randle, LTC, MC		Facility:	Eisenhower Army Medical Center	
Department/Service:	Residential Treatment Facility		Associate Investigators:	Daniel Hendricks, M.D.	
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective: To evaluate the long term effect of desipramine on cocaine dependent patients, and to evaluate the short term effects of desipramine on craving by cocaine dependent patients while on inpatient status as well monitor adverse reactions in a controlled situation.

Progress: PI has PCS'd, terminate.

DETAIL SUMMARY SHEET

Date:	2 Oct 92	Protocol #:	85-5	Status:	Ongoing
Title:	Advanced trauma life support course				
Start Date:	Jan 85	Est. Compl. Date:			
Principal Investigator(s):			Facility:	Eisenhower Army Medical Center	
Department/Service:	Surgery/Clinical Investigation		Associate Investigators:		
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:	Sep 92 Continue	

Study Objective: To provide training for physicians who are not dealing with major trauma on a day-to-day basis, and who may have to evaluate the seriously injured patient during the period immediately after injury. Also, it is intended to provide the basic knowledge and skills necessary to identify those patients whose need is for rapid assessment, resuscitation, and stabilization.

Technical Approach:

a. **Design:** The advanced trauma life support course is a two day training session in which participants are given didactic instruction followed by practical skill stations and an animal lab. Testing is accomplished by a written exam and a practical exercise in which a simulated trauma victim is resuscitated.

b. **Manpower:** Requirements as follows:

Course Director (1 MC)
 Course Administrator (MS)
 Instructors (6 MC)
 Logistical support (2 EM)
 Moulage patients (4 EM)

c. **Funding:** Administrative cost derived from Office of Medical Education.

Progress: Successful ATLS Course Feb 19-21, 33 physicians trained. Hope to conduct two sessions in FY 93.

DETAIL SUMMARY SHEET

Date:	13 Oct 92	Protocol #:	88-5	Status:	Ongoing
Title: Investigation of cryotreatment on the epiphysis of growing rabbit bones					
Start Date:			Est. Compl. Date:		
Principal Investigator(s): Roberto H. Barja, COL, MC			Facility: Eisenhower Army Medical Center		
Department/Service: Surgery/Orthopedics			Associate Investigators:		
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results: Oct 92 Continue		

Study Objective: 1) To evaluate cryotherapy times on the epiphysis of 6 week old rabbits (right femur); 2) to examine both grossly and microscopically, the effects of cryotherapy on bone growth epiphyseal closure.

Technical Approach: A cryoprobe after surgical cut-down is applied to epiphyses in the distal right femur of 6 week old rabbits. Four weeks post-cryotreatment the rabbits are euthanized, then a surgical cut-down is performed to remove the right and left femur. The pathologist then determines the gross effect on growth plates and any deformities present on the right vs the left femur. Microscopic specimens of the cryotreated epiphyses are examined to evaluate remaining potential for growth, microvascular structures, and uniformity of cryological effects.

Progress: None this FY.

DETAIL SUMMARY SHEET

Date:	14 Oct 92	Protocol #:	88-6	Status:	Ongoing
Title:	Distal thigh pain and stress transfer in uncemented total hip arthroplasties. A scintigraphic analysis				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	Scott R. Duffin, MAJ, MC		Facility:	Eisenhower Army Medical Center	
Department/Service:	Surgery/Orthopedics		Associate Investigators:	Orthopedic Residents Joseph M Erpelding, MD, MAJ, MC	
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective: To determine if anterior thigh pain in uncemented total hip arthroplasties is caused by distal stress transfer through the femur prosthesis.

Technical Approach: Routine bone scans will be done at various time intervals following cemented and uncemented total hip arthroplasties. The bone scan is an accepted method of evaluating hip prostheses, having demonstrated both prospectively and retrospectively excellent sensitivity and good specificity in detecting and defining abnormalities such as loosening, fracture, and infection.

Number of subjects enrolled to date: 77

Number of subjects enrolled for reporting period: 0

Progress: Phase I completed: comparison of cemented vs uncemented PCA hips.
Phase II will compare above to uncemented cluster/E series hips.

DETAIL SUMMARY SHEET

Date:	5 Nov 92	Protocol #:	90-25	Status:	Ongoing
Title:	A prospective randomized study of the prophylaxis of thromboembolism dihydroergotamine/heparin <i>versus</i> sodium warfarin in total joint patients				
Start Date:	Jun 90	Est. Compl. Date:			
Principal Investigator(s):	David A. Volgas, CPT, MC		Facility: Eisenhower Army Medical Center		
Department/Service:	Surgery/Orthopedics		Associate Investigators: Melissa McMillan, MAJ, MC Robert Scharstein, MAJ, MC		
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective: To compare two regimens commonly used for thromboembolism prophylaxis in the total joint patient.

Number of subjects enrolled to date: 25

Number of subjects enrolled for reporting period: 0

Progress: Study on hold pending more staff assignments.

DETAIL SUMMARY SHEET

Date:	6 Oct 92	Protocol #:	90-32	Status:	Ongoing
Title:	Training general surgery residents utilizing goat and pig models				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	Robert G. Martindale, MAJ, MC		Facility:	Eisenhower Army Medical Center	
Department/Service:	Surgery/Clinical Investigation		Associate Investigators:		
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:	Sep 92 Continue	

Study Objective: To allow the practicing and refinement of surgical approaches and techniques on animal models prior to performing the same procedure in the human.

Progress: Eight pigs used to train mainly in new laparoscopic techniques.

DETAIL SUMMARY SHEET

Date:	5 May 92	Protocol #:	90-37	Status:	Terminated
Title:	The influence of human growth hormone on post-operative recovery following major upper abdominal surgery				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	Robert G. Martindale, MAJ, MC		Facility:	Eisenhower Army Medical Center	
Department/Service:	Surgery		Associate Investigators:	Michael J. Kottas, MAJ, MS	
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective: To use hormonal manipulation to lessen the lean body tissue loss associated with a major catabolic insult.

Technical Approach: Patients will be randomized to receive either standard postoperative care and nutritional support (control) or standard care plus addition of GH (recombinant human growth hormone) starting the day prior to surgery.

Number of subjects enrolled to date: 2

Number of subjects enrolled for reporting period: 0

Progress: Desert Storm set this study back one year. Several papers evaluating this exact topic have now been published. Terminate.

DETAIL SUMMARY SHEET

Date:	21 Oct 92	Protocol #:	91-22	Status:	Terminate
Title: Training urology service physicians utilizing pig models					
Start Date:			Est. Compl. Date:		
Principal Investigator(s): Robert B. Whitmore, MAJ, MC			Facility: Eisenhower Army Medical Center		
Department/Service: Surgery/Urology			Associate Investigators: Isabello Castillo, LTC, MC		
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective: To train urology staff in technically demanding and/or infrequently performed surgical procedures.

Technical Approach: The current training of urologists will at times necessitate the use of animal models to assist the surgeon in being optimally prepared in performing certain operations, especially as regards safety and efficiency of performing said procedure.

Progress: No activity in FY 92. Terminate.

DETAIL SUMMARY SHEET

Date:	2 Oct 92	Protocol #:	91-59	Status:	Ongoing
Title:	Use of the rat model for teaching and practicing microvascular surgical technique				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	Brian K. Barnard, MAJ, MC		Facility:	Eisenhower Army Medical Center	
Department/Service:	Surgery/Orthopedics		Associate Investigators:	Orthopedic Residents	
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:	Sep 92 continue	

Study Objective: To utilize the rat model for the practice and teaching of microvascular surgical techniques.

Technical Approach: Training procedures include end-to-end, end-to-side, and side-to-side anastomosis of the femoral artery and vein, as well as, interpositional vein grafting.

Progress: Three residents have undergone training.

DETAIL SUMMARY SHEET

Date:	6 Oct 92	Protocol #:	91-81	Status:	Ongoing
Title:	Evaluation of the current routine post op feeding regimens				
Start Date:		Est. Compl. Date:	Dec 93		
Principal Investigator(s):	M. Brian Harkins, CPT, MC		Facility:	Eisenhower Army Medical Center	
Department/Service:	Surgery		Associate Investigators:	Robert G. Martindale, MAJ, MC	
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective: To determine if patients are able to tolerate a regular diet rather than clear liquids as their first P.O. intake following intraabdominal surgery.

Technical Approach: Randomized patients to alternate diets.

Number of subjects enrolled for the reporting period: 64

Progress: Study ongoing, data collection continuing.

DETAIL SUMMARY SHEET

Date:	6 Oct 92	Protocol #:	91-82	Status:	Ongoing
Title:	The effect of non-ionic surfactants on GI mucosal integrity and bacterial translocation from the gut (mice)				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	Robert G. Martindale, MAJ, MC		Facility:	Eisenhower Army Medical Center	
Department/Service:	Surgery		Associate Investigators:	James McPherson III, PhD David Turgeon, PhD, MAJ, MS	
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective: To evaluate the potential protective effects of non-ionic surfactants on GI mucosa.

Technical Approach:

Progress: Dose responses have been completed, it appears surfactants have minimal effect, if any, on preventing translocation of bacteria. Had had problems establishing adequate dose of endotoxin to use.

DETAIL SUMMARY SHEET

Date:	2 Oct 92	Protocol #:	92-3	Status:	Ongoing
Title:	Free dermal fat grafts in expanded tissue recipient pockets in the pig				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	Richard A. Beck, MAJ, MC		Facility:	Eisenhower Army Medical Center	
Department/Service:	Surgery/Otolaryngology-HNS		Associate Investigators:		
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:	Sep 92 Continue	

Study Objective: To determine if free dermal fat grafts have improved survival and predictable rates of resorption after implantation in expanded tissue pockets in the pig model. Also, to determine the histologic characteristics of the capsule which forms around expanded/nonexpanded silicone prostheses, and the free dermal fat grafts at specified intervals following transplantation.

Technical Approach:

Progress: Have had scheduling conflicts during department staffing shortage. Anticipate start up in the coming year.

DETAIL SUMMARY SHEET

Date:	6 Oct 92	Protocol #:	92-4	Status:	Ongoing
Title:	The effect of pentoxifyline vs allopurinol on sigmoid mucosal ischemia during abdominal aortic surgery				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	William C. Calton, CPT, MC		Facility:	Eisenhower Army Medical Center	
Department/Service:	Surgery		Associate Investigators:	Robert G. Martindale, MAJ, MC Manuel F. Ramirez, LTC, MC	
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective: This study will make considerable use of a new noninvasive technique to measure the adequacy of tissue oxygenation called tonometry.

Technical Approach: Tonometry relies upon the fact that CO₂ is freely permeable between the lumen, luminal fluid and superficial layer of the mucosa. By measuring CO₂ in the luminal fluid and simultaneously measuring arterial blood gases, mucosal pH can be calculated using the Henderson-Hasselbalch equation. The validity and safety of this technique has now been substantiated in several studies.

Progress: One patient has been enrolled, study continues.

DETAIL SUMMARY SHEET

Date:	6 Oct 92	Protocol #:	92-5	Status:	Completed
Title:	Evaluation of deployable CT scanner				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):			Facility:		
Michael R. St Jean, CPT, MC			Eisenhower Army Medical Center		
Department/Service:			Associate Investigators:		
Surgery					
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective:

Technical Approach:

Progress: Study completed.

DETAIL SUMMARY SHEET

Date:	6 Oct 92	Protocol #:	92-11	Status:	Completed
Title:	A multicenter, double-blind, randomized, comparative study of the efficacy and safety of intravenous temafloxacin <i>versus</i> imipenem-cilastatin sodium in the treatment of intra-abdominal infection				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	Robert G. Martindale, MAJ, MC		Facility:	Eisenhower Army Medical Center	
Department/Service:	Surgery/General Surgery		Associate Investigators:	Michael P. Byrne, LTC, MC Victor L. Modesto, MAJ, MC	
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective: To determine the efficacy and safety of intravenously administered temafloxacin when compared with that of imipenem-cilastatin sodium.

Technical Approach: Treatment will follow outline in Abbott Laboratories' protocol.

Subjects enrolled to date: 9

Progress: Study terminated when Abbott withdrew drug from market. There were no adverse events at DDEAMC. All enrollees had a good outcome.

DETAIL SUMMARY SHEET

Date:	6 Oct 92	Protocol #:	92-12	Status:	Ongoing
Title:	Implications of urinary phosphate level after thyroid or parathyroid surgery				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	William J. Kaiser, CPT, MC		Facility:	Eisenhower Army Medical Center	
Department/Service:	Surgery/General Surgery		Associate Investigators:	Robert G. Martindale, MAJ, MC Michael P. Byrne, LTC, MC	
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective: To prospectively follow serum Ca^{2+} and urinary PO_4 in patients undergoing thyroid/parathyroid surgery; and to evaluate if it has any predictive effect.

Technical Approach:

Subjects enrolled to date: 3

Progress: Data being collected.

DETAIL SUMMARY SHEET

Date:	6 Oct 92	Protocol #:	92-13	Status:	Ongoing
Title:	The effect of IV pentoxifylline on endotoxin mediated small bowel mucosal ischemia using the pig model				
Start Date:			Est. Compl. Date:	Dec 93	
Principal Investigator(s):	William C. Calton, Jr., CPT, MC		Facility:	Eisenhower Army Medical Center	
Department/Service:	Surgery/General Surgery		Associate Investigators:	Robert G. Martindale, MAJ, MC Michael P. Byrne, LTC, MC David Turgeon, PhD, MAJ, MS	
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective: To determine if pentoxifylline can attenuate the splanchnic vasoconstriction seen with endotoxin.

Technical Approach:

Progress: Two pigs have been used to work out technical parameters.

DETAIL SUMMARY SHEET

Date:	6 Oct 92	Protocol #:	92-19	Status:	Completed
Title:	Evaluation of laparoscopic gastrostomy technique				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	Robert G. Martindale, MAJ, MC		Facility:	Eisenhower Army Medical Center	
Department/Service:	Surgery/General Surgery		Associate Investigators:	Victor Modesto, MAJ, MC Michael Byrne, LTC, MC	
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective: To develop a laparoscopic gastrostomy technique.

Technical Approach: As outlined in Ross Labs protocol.

Subjects enrolled to date: 2

Progress: Data sent in to Ross Labs, study is completed.

DETAIL SUMMARY SHEET

Date:	21 Oct 92	Protocol #:	92-21	Status:	Ongoing
Title:	A comparison of rigidity of combat external fixators				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	Scott R. Duffin, MAJ, MC		Facility:	Eisenhower Army Medical Center	
Department/Service:	Surgery/Orthopedics		Associate Investigators:	Joseph Erpelding, LTC, MC	
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective:

Technical Approach:

Subjects enrolled to date:

Progress: No reportable data.

DETAIL SUMMARY SHEET

Date:	6 Oct 92	Protocol #:	92-26	Status:	Ongoing
Title:	The effects of somatostatin analog (octreotide acetate) on wound healing in the mouse model				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	Robert G. Martindale, MAJ, MC		Facility:	Eisenhower Army Medical Center	
Department/Service:	Surgery/General Surgery		Associate Investigators:	Donald E. Sutherland, PhD, MAJ, MS William Calton, Jr, CPT, MC Sam Miller, CPT, MC	
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective: To determine if the somatostatin analog affects wound healing.

Technical Approach:

Progress: Techniques for PTFE implantation have been perfected. Awaiting new FY to be able to buy hydroxyproline standards for use in assay.

DETAIL SUMMARY SHEET

Date:	6 Oct 92	Protocol #:	92-27	Status:	Ongoing
Title:	Natural history of free gallstones within the peritoneum in a rabbit model and mouse model				
Start Date:			Est. Compl. Date:	Dec 93	
Principal Investigator(s):			Facility:		
	Ray Workman, CPT, MC			Eisenhower Army Medical Center	
Department/Service:			Associate Investigators:		
	Surgery/General Surgery			Michael Byrne, LTC, MC Robert G. Martindale, MAJ, MC Thomas R. Gadacz, M.D.	
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective: As above.

Technical Approach:

Progress: Animals have been ordered.

DETAIL SUMMARY SHEET

Date:	6 Oct 92	Protocol #:	92-28	Status:	Completed
Title:	Tube verifier efficacy study				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	Robert G. Martindale, MAJ, MC		Facility:	Eisenhower Army Medical Center	
Department/Service:	Surgery/General Surgery		Associate Investigators:		
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective: To describe tuber verifier efficacy when utilized for feeding tube intubation of the stomach and the small bowel. To describe tube verifier efficacy when utilized for verifying feeding tube position in the stomach and the small bowel over time.

Technical Approach: As outlined in Ross Laboratories' protocol.

Subjects enrolled to date: 12

Progress: No complications in DDEAMC patients. Study completed.

DETAIL SUMMARY SHEET

Date:	6 Oct 92	Protocol #:	92-29	Status:	Completed
Title:	Laparoscopic jejunostomy efficacy study				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	Robert G. Martindale, MAJ, MC		Facility:	Eisenhower Army Medical Center	
Department/Service:	Surgery/General Surgery		Associate Investigators:		
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective: To develop a laparoscopic jejunostomy technique, to evaluate the safety and efficacy of a J-tube, and to compare the efficacy of two different J-tubes.

Technical Approach: As outlined in Ross Laboratories' protocol.

Subjects enrolled to date: 2

Progress: Excellent results, patients tolerated laparoscopic jejunostomy much better than open jejunostomy.

DETAIL SUMMARY SHEET

Date:	6 Oct 92	Protocol #:	92-52	Status:	Ongoing
Title:	Laparoscopic appendectomy vs standard appendectomy				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	Thomas Taylor, CPT, MC		Facility:	Eisenhower Army Medical Center	
Department/Service:	Surgery/General Surgery		Associate Investigators:	Victor L. Modesto, MAJ, MC Paul A. LePage, MAJ, MC	
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective: To compare hospital stay, amount of post-operative pain medications, amount of post-operative complications such as wound infection and abscess formation, and the percentage of false positives to that of open appendectomy. We also wish to become proficient in the art of laparoscopic appendectomy.

Technical Approach: Open appendectomy will be performed in the standard fashion utilizing a Rockey Davis incision. An extension of this incision may be utilized as deemed necessary by the senior surgeon performing the case. All open appendectomies will undergo irrigation of the pelvis in the reverse trendelenburg position.

Subjects enrolled to date: 0

Progress: Study held up because of OR budget constraints.

DETAIL SUMMARY SHEET

Date:	23 Jan 92	Protocol #:	91-26	Status:	Completed
Title:	SWOG 8516 (INT 0067, EST 3487): A phase III comparison of CHOP vs m-BACOD vs Pro-Mace-CytaBOM vs MACOP-B in patients with intermediate or high-grade Non-Hodgkins lymphoma				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	Mark R. Keaton, MAJ, MC		Facility:	Eisenhower Army Medical Center	
Department/Service:	Medicine/Oncology		Associate Investigators:	Richard S. Foulke, MAJ, MC Jayanti K. Sen, COL, MC	
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective: To compare in a randomized group-wide setting the complete response rate, response duration and survival of patients with intermediate and high grade non-Hodgkin's lymphoma treated with one of four combination chemotherapy regimens CHOP, m-BACOB, ProMACE-CytaBOM, or MACOP-B. To compare the toxicities of each regimen in this patient population.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled for reporting period: 0

Progress: Accrual goal met, study closed by SWOG.

DETAIL SUMMARY SHEET

Date:	20 Oct 92	Protocol #:	91-27	Status:	Ongoing
Title:	SWOG 8809 - A phase III study of alpha-interferon consolidation following chemotherapy with Promace-MOPP (Day 1-8) in patients with low grade malignant lymphomas				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	Mark R. Keaton, MAJ, MC		Facility:	Eisenhower Army Medical Center	
Department/Service:	Medicine/Oncology		Associate Investigators:	Richard S. Foulke, MAJ, MC Jayanti K. Sen, COL, MC Don Shaffer, MAJ, MC Robert Krywicki, MAJ, MC	
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:	Feb 92 Ccontinue	

Study Objective: To compare the disease-free survival of patients with low grade malignant lymphoma who receive alpha interferon consolidation therapy after intensive induction with chemotherapy-radiation therapy, to those who receive induction therapy alone. To determine the complete response rate, response duration and survival of low grade lymphoma patients treated with ProMACE-MCPP (day 1-8). To compare the toxicities of induction and induction plus consolidation therapy in this patient population.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled for reporting period: 1

Progress: One patient on therapy.

DETAIL SUMMARY SHEET

Date:	20 Oct 92	Protocol #:	91-29	Status:	Ongoing
Title:	SWOG 8854 (ECOG 1189, NCCTG 898051) Prognostic value of cytometry measurements of breast cancer DNA from postmenopausal patients with involved nodes and receptor positive tumors: A comparison protocol to SWOG 8814				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	Mark R. Keaton, MAJ, MC		Facility:	Eisenhower Army Medical Center	
Department/Service:	Medicine/Oncology		Associate Investigators:	Richard S. Foulke, MAJ, MC Robert D. Ranlett, LTC, MC Arthur Wozniak, LTC, MS Don Shaffer, MAJ, MC Robert Krywicki, MAJ, MC	
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:	Feb 92 Continue	

Study Objective: To determine if ploidy analysis of breast cancer by routine clinical flow cytometry (FCM) technique can predict response to therapy and survival of patients registered to SWOG 8814. To determine if ploidy analysis by image processing technique more accurately predicts patient response to therapy and survival than ploidy analysis by FCM.

Technical Approach: As outlined in SWOG protocol.

Number of subjects enrolled for reporting period: 0

Progress: None to date.

DETAIL SUMMARY SHEET

Date:	20 Oct 92	Protocol #:	91-30	Status:	Ongoing
Title:	SWOG 8814 (ECOG-4188, NCCTG-883051) Phase III Comparison of adjuvant chemoendocrine therapy with CAF and concurrent or delayed tamoxifen to tamoxifen alone in postmenopausal patients with involved axillary nodes and positive receptors				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	Mark R. Keaton, MAJ, MC		Facility:	Eisenhower Army Medical Center	
Department/Service:	Medicine/Oncology, Pathology		Associate Investigators:	Richard S. Foulke, MAJ, MC Robert D. Ranlett, LTC, MC Arthur Wozniak, LTC, MS Don Shaffer, MAJ, MC Robert Krywicki, MAJ, MC	
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:	Feb 92 Continue	

Study Objective: To compare disease-free survival and overall survival of postmenopausal primary breast cancer patients with involved axillary nodes and positive estrogen and/or progesterone receptors treated with standard adjuvant therapy with long-term tamoxifen, or with chemoendocrine therapy with CAF, followed by long-term tamoxifen, or with concurrent chemoendocrine therapy with tamoxifen and CAF. To compare the relative toxicity of the three therapies.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled for reporting period: 0

Progress: None to date.

DETAIL SUMMARY SHEET

Date:	20 Oct 92	Protocol #:	91-31	Status:	Ongoing
Title:	SWOG 8897 (EST-2188, CALGB-8897, INT0102) Phase III Comparison of adjuvant chemotherapy with or without endocrine therapy in high-risk, node negative breast cancer patients, and a natural history follow-up study in low-risk, node negative patients				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	Mark R. Keaton, MAJ, MC		Facility:	Eisenhower Army Medical Center	
Department/Service:	Medicine/Oncology, Pathology		Associate Investigators:	Richard S. Foulke, MAJ, MC Robert D. Ranlett, LTC, MS Arthur Wozniak, LTC, MS Don Shaffer, MAJ, MC Robert Krywicki, MAJ, MC	
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:	Feb 92 Continue	

Study Objective: To compare disease-free survival (DFS) and overall survival (S) of high risk primary breast cancer patients with negative axillary lymph nodes treated with standard adjuvant chemotherapy with CMF for six cycles or with chemotherapy using CAF for six cycles. To assess the value of the addition of tamoxifen for five years compared to no tamoxifen in these patients. To compare the relative toxicity of the therapies. To assess the prognostic significance of DNA flow cytometry in patients with small, occult invasive breast cancer treated by local therapy only. To evaluate the DFS and S of low risk invasive breast cancer determined by receptor status, tumor size and S phase treated by local therapy only.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled for reporting period: 1

Progress: One patient on therapy.

DETAIL SUMMARY SHEET

Date:	20 Oct 92	Protocol #:	91-32	Status:	Completed
Title:	SWOG 8899 (INT 0089) A Prospectively randomized trial of low dose leucovorin + 5-FU, high dose leucovorin + 5-FU, levamisole + 5-FU, or low leucovorin + 5-FU + levamisole following curative resection in selected patients with Ducks' B or C colon cancer				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):			Facility:		
Mark R. Keaton, MAJ, MC			Eisenhower Army Medical Center		
Department/Service:			Associate Investigators:		
Medicine/Oncology, Pathology			Richard S. Foulke, MAJ, MC Paulino O. Vasallo, COL, MC		
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:		
			Feb 92 Continue		

Study Objective: To independently assess the effectiveness of each regimen: 5-FU _ low-dose leucovorin. 5-FU + high-dose leucovorin, 5-FU + levamisole and 5-FU + low-dose leucovorin + levamisole as surgical adjuvant therapy for resectable colon cancer. To perform comparisons of treatment arms, to determine the optimal adjuvant program in efficacy and tolerability. To compare two 5-FU + leucovorin regimens, known to be effective in advanced disease. To assess the efficacy of the three leucovorin-containing arms to the standard 5-FU + levamisole combination. To assess the contribution of levamisole in the comparison of 5-FU + low-dose leucovorin to the same regimen with the addition of levamisole.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled for reporting period: 2

Progress: Accrual goal met, study closed by SWOG.

DETAIL SUMMARY SHEET

Date:	23 Jan 92	Protocol #:	91-33	Status:	Completed
Title:	SWOG 8900 A Phase II pilot of VAD and VAD/verapamil for refractory multiple myeloma				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	Mark R. Keaton, MAJ, MC		Facility:	Eisenhower Army Medical Center	
Department/Service:	Medicine/Oncology, Pathology		Associate Investigators:	Richard S. Foulke, MAJ, MC Jayanti K. Sen, COL, MC	
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective: To estimate the response rate and response duration with chemotherapy alone (VAD) and chemotherapy plus the chemomodifier, verapamil (VAD/V), in patients who have failed previous combination chemotherapy. To investigate the toxicities of these two treatments. To evaluate the presence and prognostic significance of Ki-67 and P-glycoprotein in multiple myeloma.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled for reporting period: 0

Progress: Accrual goal met, study closed by SWOG.

DETAIL SUMMARY SHEET

Date:	20 Oct 92	Protocol #:	91-34	Status:	Ongoing
Title:	SWOG 8931 (EST-3189, INT-0108) Phase III Comparison of Cyclophosphamide, Doxorubicin, and 5-Fluorouracil (CAF) and a 16-Week Multi-Drug Regimen as Adjuvant Therapy for Patients with Hormone Receptor Negative, Node Positive Breast Cancer				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	Mark R. Keaton, MAJ, MC		Facility:	Cisenhower Army Medical Center	
Department/Service:	Medicine/Oncology, Pathology		Associate Investigators:	Richard S. Foulke, MAJ, MC Paulino O. Vasallo, COL, MC Don Shaffer, MAJ, MC Robert Krywicki, MAJ, MC	
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:	Feb 92 Continue	

Objective: To compare disease-free and overall survival in node positive receptor negative breast cancer patients receiving adjuvant CAF or a 16-week multi-drug chemotherapy regimen. To compare toxicities of adjuvant CAF and a 16-week multi-drug regimen.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled for reporting period: 1

Progress: One patient on therapy.

DETAIL SUMMARY SHEET

Date:	20 Oct 92	Protocol #:	91-35	Status:	Ongoing
Title:	SWOG 8947 Central lymphoma serum repository protocol. (Companion study to SWOG 8516, 8736, 8809 or 8816)				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	Mark R. Keaton, MAJ, MC		Facility:	Eisenhower Army Medical Center	
Department/Service:	Medicine/Oncology, Pathology		Associate Investigators:	Richard S. Foulke, MAJ, MC Rodney G. Day, LTC, MS Robert Krywicki, MAJ, MC Don Shaffer, MAJ, MC	
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:	Feb 92 Continue	

Study Objective: To establish a central lymphoma serum repository that will serve as a resource to provide specimens for current and future scientific studies. To utilize the SWOG database to perform clinicopathologic correlations with the results of those studies.

Technical Approach: Blood sample will be drawn and shipped to the Serum Repository Laboratory for testing.

Number of subjects enrolled for reporting period: 2

Progress: Two patients on therapy.

DETAIL SUMMARY SHEET

Date:	20 Oct 92	Protocol #:	91-36	Status:	Ongoing
Title:	SWOG 9037 Prediction of recurrence and survival in node negative breast cancer patients using a panel of prognostic factors				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	Mark R. Keaton, MAJ, MC		Facility:	Eisenhower Army Medical Center	
Department/Service:	Medicine/Oncology, Pathology		Associate Investigators:	Richard S. Foulke, MAJ, MC Robert D. Ranlett, LTC, MC Arthur Wozniak, LTC, MS Don Shaffer, MAJ, MC Robert Krywicki, MAJ, MC	
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:	Feb 92 Continue	

Study Objective: To measure histologic and nuclear grade, estrogen and progesterone receptors, HER-2 oncogene, cathepsin D, EGF receptor, PS2, hsp27, 70 and 90, in paraffin-embedded histopathological specimens from lymph node-negative breast cancer patients. To correlate the above factors with biological and clinical features including recurrence and survival in patients entered on SWOG 8897.

Technical Approach: Paraffin-embedded histopathological specimens will be submitted to a San Antonio laboratory for measurements.

Number of subjects enrolled for reporting period: 0

Progress: None to date.

DETAIL SUMMARY SHEET

Date:	20 Oct 92	Protocol #:	91-41	Status:	Ongoing
Title:	SWOG 8736 Treatment of localized non-Hodgkin's lymphoma: Comparison of chemotherapy (CHOP) to chemotherapy plus radiation therapy				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	Mark R. Keaton, MAJ, MC		Facility:	Eisenhower Army Medical Center	
Department/Service:	Medicine/Oncology, Pathology		Associate Investigators:	Richard S. Foulke, MAJ, MC Jayanti K. Sen, COL, MC Don Shaffer, MAJ, MC Robert Krywicki, MAJ, MC	
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:	Feb 92 Continue	

Study Objective: The primary study objective is to evaluate, in a cooperative group setting, the difference in survival, time to treatment failure and toxicity of two curative approaches to the treatment of patients with localized, intermediate or high grade, non-Hodgkin's lymphoma. The first treatment approach is chemotherapy using Cyclophosphamide, Doxorubicin, Vincristine and Prednisone (CHOP) for eight cycles. The second uses CHOP for three cycles followed by involved field radiation therapy.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled for the reporting period: 1

Progress: One patient on therapy.

DETAIL SUMMARY SHEET

Date:	20 Oct 92	Protocol #:	91-42	Status:	Ongoing
Title:	SWOG 9040 Intergroup rectal adjuvant protocol, A Phase III study				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	Mark R. Keaton, MAJ, MC		Facility:	Eisenhower Army Medical Center	
Department/Service:	Medicine/Oncology, Pathology		Associate Investigators:	Richard S. Foulke, MAJ, MC Paulino O. Vasallo, COL, MC Don Shaffer, MAJ, MC Robert Krywicki, MAJ, MC	
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:	Feb 92 Continue	

Study Objective: To determine the relative efficacy of 5-FU, 5-FU and leucovorin, 5-FU and levamisole, and 5-FU, leucovorin and levamisole when combined with pelvic radiation therapy in the treatment of Stages B-2 and C (TNM Stage II and III) rectal cancer. End points used will include local recurrence rates, probability of distant metastases, disease free survival rates, and overall survival. 5-FU with radiation therapy will comprise the control arm of the study. This will be a 4-armed study with the same radiation therapy program in all arms, but with varying drug regimens.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled for the reporting period: 0

Progress: None to date.

DETAIL SUMMARY SHEET

Date:	20 Oct 92	Protocol #:	91-48	Status:	Completed
Title:	SWOG 8598 (RTOG-85-1) Prospective trial for localized cancer of the esophagus: Comparing radiation as a single modality to the combination of radiation therapy and chemotherapy, Phase III Intergroup				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	Mark R. Keaton, MAJ, MC		Facility:	Eisenhower Army Medical Center	
Department/Service:	Medicine/Oncology, Pathology		Associate Investigators:	Richard S. Foulke, MAJ, MC Paulino O. Vasallo, COL, MC	
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:	Feb 92 Continue	

Study Objective: To determine the role of chemotherapy for a potentially curable subset of patients with adeno or squamous cell cancer of the esophagus. Specifically, to determine if the combination of chemotherapy and radiation will add to the overall survival and cure of patients treated with the combination when compared to patients treated by radiation alone. To determine if the patterns of recurrence for patients treated with the combination of chemotherapy and radiation differs from those patients treated with radiation alone.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled for the reporting period: 0

Progress: Accrual goal met, study closed by SWOG.

DETAIL SUMMARY SHEET

Date:	20 Oct 92	Protocol #:	91-49	Status:	Completed
Title:	SWOG 8792 Phase III study of Alpha-nl (Wellferon) as adjuvant treatment for resectable renal cell carcinoma				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	Mark R. Keaton, MAJ, MC		Facility:	Eisenhower Army Medical Center	
Department/Service:	Medicine/Oncology, Pathology		Associate Investigators:	Richard S. Foulke, MAJ, MC Jayanti K. Sen, COL, MC	
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:	Feb 92 Continue	

Study Objective: To assess in a controlled fashion the effectiveness of interferon alfa-nl (Wellferon) as a surgical adjuvant in patients with renal cell carcinoma.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled for the reporting period: 1

Progress: Accrual goal met, study closed by SWOG.

DETAIL SUMMARY SHEET

Date:	20 Oct 92	Protocol #:	91-50	Status:	Ongoing
Title:	SWOG 8851 Phase III comparison of combination chemotherapy (CAF) and chemohormonal therapy (CAF + Zoladex or CAF + Zoladex + Tamoxifen) in premenopausal women with axillary node-positive, receptor-positive breast cancer -- intergroup				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	Mark R. Keaton, MAJ, MC		Facility:	Eisenhower Army Medical Center	
Department/Service:	Medicine/Oncology, Pathology		Associate Investigators:	Richard S. Foulke, MAJ, MC Robert D. Ranlett, LTC, MC Don Shaffer, MAJ, MC Robert Krywicki, MAJ, MC	
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:	Feb 92 Continue	

Study Objective: To compare the recurrence rates, disease-free intervals (DFI), and hormone-receptor-positive survival for premenopausal women with axillary lymph node-positive breast cancer given adjuvant therapy with chemotherapy (CAF) alone or chemotherapy (CAF) followed by Zoladex (Z) or chemotherapy (CAF) followed by Zoladex plus Tamoxifen (X + T). We will compare CAF with CAF + Z and CAF + Z with CAF + Z + T. To compare the relative toxicities of these 3 regimens. To assess the effect of CAF, CAF + Z, and CAF + Z + T on hormone levels (LH, FSH, and estradiol) in premenopausal women treated with these adjuvant therapies.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled for reporting period: 1

Progress: One patient on therapy.

DETAIL SUMMARY SHEET

Date:	23 Jan 92	Protocol #:	91-51	Status:	Terminated
Title:	SWOG 8857 Alternating Cisplatin/VP-16 with continuous CAV and consolidation chemotherapy for extensive small cell lung cancer with PCI for complete responders				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	Mark R. Keaton, MAJ, MC		Facility:	Eisenhower Army Medical Center	
Department/Service:	Medicine/Oncology, Pathology		Associate Investigators:	Richard S. Foulke, MAJ, MC Robert D. Ranlett, LTC, MC	
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective: To assess response rate (especially rate of CR) and toxicity of a "dose intensive" approach to induction chemotherapy in which cisplatin/VP-16 is alternated with cyclophosphamide, adriamycin and vincristine: consolidation therapy will be given to responders with one cycle of each induction regimen, coupled with prophylactic brain irradiation in CR patients. To measure survival in patients so treated.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled: 0

Progress: Study closed by SWOG.

DETAIL SUMMARY SHEET

Date:	13 ct 92	Protocol #:	91-53	Status:	Ongoing
Title:	SWOG 8952 Treatment of advanced Hodgkin's disease - A randomized Phase III study comparing ABVD vs MOPP/ABV hybrid				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	Mark R. Keaton, MAJ, MC		Facility:	Eisenhower Army Medical Center	
Department/Service:	Medicine/Oncology, Pathology		Associate Investigators:	Richard S. Foulke, MAJ, MC Jayanti K. Sen, MAJ, MC	
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective: To compare ABVD to the MOPP/ABV hybrid as therapy for patients with advanced Hodgkin's disease in terms of complete response rates, disease-free survival, failure-free survival and both immediate and long-term toxicities. To compare the rate of drug delivery of the anti-neoplastic agents, especially the comparative dose rate of ABV in the two treatment groups. To examine the prognostic importance of time to response, performance status, age, presence of bulky disease, C-reactive protein, erythrocyte sedimentation rate, and prior radiotherapy on survival.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled for reporting period: 0

Progress: None.

DETAIL SUMMARY SHEET

Date:	20 Oct 92	Protocol #:	91-54	Status:	Completed
Title:	SWOG 8997 Phase III Chemotherapy of disseminated advanced Stage testicular cancer with cisplatin plus etoposide with either bleomycin or ifosfamide				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	Mark R. Keaton, MAJ, MC		Facility:	Eisenhower Army Medical Center	
Department/Service:	Medicine/Oncology, Pathology		Associate Investigators:	Richard S. Foulke, MAJ, MC Jayanti K. Sen, COL, MC	
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:	Feb 92 Continue	

Study Objective: To determine the objective response rate and duration of remission of BEP compared to VIP combination chemotherapy. To determine the toxicity of VIP compared to BEP combination chemotherapy. To confirm the efficacy and toxicity of intravenous Mesna as a urothelial protective agent.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled for the reporting period: 2

Progress: Accrual goal met, study closed by SWOG.

DETAIL SUMMARY SHEET

Date:	20 Oct 92	Protocol #:	91-55	Status:	Ongoing
Title:	SWOG 9013 A prospective randomized comparison of combined modality therapy for squamous carcinoma of the esophagus: Chemotherapy plus surgery alone for patients with local regional disease. Phase III intergroup				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	Mark R. Keaton, MAJ, MC		Facility:	Eisenhower Army Medical Center	
Department/Service:	Medicine/Oncology		Associate Investigators:	Richard S. Foulke, MAJ, MC Paulino O. Vasallo, COL, MC Don Shaffer, MAJ, MC Robert Krywicki, MAJ, MC	
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:	Feb 92 Continue	

Study Objective: To compare, using a prospective controlled randomized study design, the outcomes of therapy of surgery alone, versus pre- and post-operative chemotherapy and surgery for patients with local regional esophageal cancer. Outcome is defined as survival and relapse pattern. To assess the toxicities of a multimodality approach to esophageal carcinoma involving systemic chemotherapy and surgery. The toxicities of surgical resection, as initial therapy or following chemotherapy will be assessed as operative morbidity and mortality. To compare the local and distinct control rates with the two approaches and to define the pattern of failure. To compare the impact on overall and disease free survival of multimodality therapy with surgery alone.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled for reporting period: 1

Progress: One patient on therapy.

DETAIL SUMMARY SHEET

Date:	20 Oct 92	Protocol #:	91-66	Status:	Completed
Title:	SWOG 9009 Pilot study of analysis of lymphocytic subsets and natural killer activity after treatment with levamisole				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):			Facility:		
Mark R. Keaton, MAJ, MC			Eisenhower Army Medical Center		
Department/Service:			Associate Investigators:		
Medicine/Oncology, Pathology			Richard S. Foulke, MAJ, MC		
Key Words:			Jayanti K. Sen, COL, MC		
Accumulative MEDCASE Cost:			Periodic Review Results:		
			Feb 92 Continue		

Study Objective: This companion protocol will analyze selected aspects of the immune response in these patients with the following objectives: 1) Describe the effect of levamisole on lymphocyte subsets in the peripheral blood over time in patients receiving adjuvant levamisole. 2) Describe the effect of levamisole on peripheral blood "natural killer" cytotoxicity over time in patients receiving adjuvant levamisole.

Technical Approach: Therapy will follow schema outlined in SWOG

Progress: No patients enrolled at DDEAMC. Accrual goal met, study closed by SWOG.

DETAIL SUMMARY SHEET

Date:	20 Oct 92	Protocol #:	91-67	Status:	Ongoing
Title:	SWOG 9012 Evaluation of low dose alpha-interferon in patients with advanced renal cell carcinoma				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):			Facility:		
	Mark R. Keaton, MAJ, MC			Eisenhower Army Medical Center	
Department/Service:			Associate Investigators:		
	Medicine/Oncology, Pathology			Richard S. Foulke, MAJ, MC Jayanti K. Sen, COL, MC Don Shaffer, MAJ, MC Robert Krywicki, MAJ, MC	
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:		
				Feb 92 Continue	

Study Objective: The objectives of this Phase II study of low dose alpha-interferon in patients with advanced renal cell carcinoma, Stage II-IV, are to: 1) evaluate the likelihood of response in order to assess whether low dose alpha-interferon should be advanced to further studies and, 2) evaluate the qualitative and quantitative toxicities.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled: 0

Progress: None.

DETAIL SUMMARY SHEET

Date:	20 Oct 92	Protocol #:	91-68	Status:	Ongoing
Title:	SWOG 9028 A Phase III Randomized trial of combination therapy for multiple myeloma. Comparison of 1) VAD to VAD/Verapamil/Quinine for induction with crossover to VAD/Verapamil/Quinine for VAD induction failures; 2) Alpha-2-b Interferon plus prednisone for remission maintenance				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	Mark R. Keaton, MAJ, MC		Facility:	Eisenhower Army Medical Center	
Department/Service:	Medicine/Oncology, Pathology		Associate Investigators:	Richard S. Foulke, MAJ, MC Jayanti K. Sen, COL, MC Don Shafer, MAJ, MC Robert Krywicki, MAJ, MC	
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:	Feb 92 Continue	

Study Objective: To compare the effectiveness of the VAD chemotherapy regimen when administered alone or in combination with chemosensitizers (verapamil/quinine) intended to block the emergence of multidrug resistance during remission induction in previously untreated patients with multiple myeloma. The effectiveness of VAD plus verapamil and quinine for non-responders and progressors of the VAD induction regimen will also be investigated. This will be evaluated in terms of relapse-free and overall survival and P-glycoprotein expression prior to therapy and at the end of induction therapy in relation to the induction therapy arm. To compare the value of Intron-A (alpha-2b interferon) maintenance versus Intron-A plus prednisone for patients proven to achieve at least partial remission (50% tumor regression). The effectiveness of the two maintenance arms will be compared in terms of the duration of relapse-free survival and overall survival from the time of randomization to maintenance therapy. The time from relapse to death will also be assessed in relation to objectives 1 and 2. To evaluate the presence and prognostic significance of Ki-67 and P-glycoprotein in multiple myeloma via serial studies of bone marrow myeloma cells by immunophenotyping. These immunophenotypic markers will be assessed prior to therapy, after completion of induction chemotherapy and/or at the time of relapse and related to clinical findings of drug-sensitivity or resistance to the treatment administered. Moreover, the expression of P-glycoprotein will be related to relapse free and overall survival and to whether the patient receives chemosensitizers along with VAD chemotherapy to determine whether the sensitizers inhibited the development of P-glycoprotein expression. To evaluate the relationship between the magnitude of cytoreduction and survival. To evaluate the significance of pretreatment serum lactic dehydrogenase (LDH) as a marker for aggressive myeloma.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled: 0

Progress: None.

DETAIL SUMMARY SHEET

Date:	14 Oct 92	Protocol #:	91-69	Status:	Ongoing
Title:	SWOG 9111 (EST-1690) Post-operative adjuvant interferon alpha-2 in resected high risk primary and regionally metastatic melanoma, intergroup				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	Mark R. Keaton, MAJ, MC		Facility:	Eisenhower Army Medical Center	
Department/Service:	Medicine/Oncology, Pathology		Associate Investigators:	Richard S. Foulke, MAJ, MC Jayanti K. Sen, COL, MC Don Shaffer, MAJ, MC Robert Krywicki, MAJ, MC	
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:	Feb 92 Continue	

Study Objective: To establish the efficacy of 1 year at maximally tolerable dosages (IV and SC) interferon alpha-2 as an adjuvant to increase the disease free interval and overall survival in patients at high risk for recurrence after definitive surgery for deep primary lesions or after regional lymph node recurrence. To evaluate the efficacy and tolerance of long-term interferon alpha-2 at 3 MU/d (Sc TIW) as an adjuvant to increase the disease-free survival and overall survival of patients at high risk for recurrence after definitive surgery for deep primary lesions or after regional lymph node recurrence with melanoma, in comparison to 1 year of treatment of maximally tolerable dosages.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled to date: 0

Progress: None.

DETAIL SUMMARY SHEET

Date:	14 Oct 92	Protocol #:	91-70	Status:	Ongoing
Title:	SWOG 9125 A Phase II trial of CVAD/Verapamil/Quinine for treatment of non-Hodgkin's lymphoma				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	Mark R. Keaton, MAJ, MC		Facility:	Eisenhower Army Medical Center	
Department/Service:	Medicine/Oncology, Pathology		Associate Investigators:	Richard S. Foulke, MAJ, MC Jayanti K. Sen, COL, MC Don Shaffer, MAJ, MC Robert Krywicki, MAJ, MC	
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:	Feb 92 Continue	

Study Objective: To evaluate the effectiveness of the CVAD chemotherapy regimen (cyclophosphamide, vincristine, doxorubicin and dexamethasone) when administered in combination with chemosensitizers (verapamil and quinine) which are intended to block the emergence of multidrug resistance in previously untreated patients with intermediate and high grade non-Hodgkin's lymphomas. The effectiveness of CVAD plus verapamil and quinine will be based on the estimate of the complete response rate and the time to treatment failure. To assess the toxicities and side effects associated with the CVAD regimen when combined with verapamil and quinine. A secondary objective is to further investigate the utility of the proliferative rate (determined by Ki-67 monoclonal antibody), the importance of cell-cell recognition molecules (using a panel of monoclonal antibodies specific for several cell recognition antigens), the role of host response (using markers of tumor infiltrating T-cells in B-cell lymphomas) and the value of detectable levels of P-glycoprotein as prognostic indicators of outcome (see companions study SWOG 8819). A secondary objective is to further utilize the central serum repository enabling clinicopathologic correlations with the results of studies on the material collected (see companion study SWOG 8947).

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled: 0

Progress: None.

DETAIL SUMMARY SHEET

Date:	14 Oct 92	Protocol #:	92-6	Status:	Ongoing
Title:	SWOG 9008 Trial of adjuvant chemoradiation after gastric resection for adenocarcinoma, Phase III				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	Mark R. Keaton, MAJ, MC		Facility:	Eisenhower Army Medical Center	
Department/Service:	Medicine/Oncology, Pathology		Associate Investigators:	Richard S. Foulke, MAJ, MC Paulino O. Vasallo, LTC, MC Don Shaffer, MAJ, MC Robert Krywicki, MAJ, MC	
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:	Feb 92 Continue	

Study Objective: 1) A comparison of overall and disease free survival between patients being treated with surgical resection only and those being treated with surgery plus adjuvant therapy. 2) A comparison of incidence and patterns of disease failure between surgery and surgery plus adjuvant therapy treated patients. 3) An assessment of patient tolerance of upper abdominal chemoradiation after gastric resection.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Subjects enrolled to date: 0

Progress: None.

DETAIL SUMMARY SHEET

Date:	14 Oct 92	Protocol #:	92-7	Status:	Ongoing
Title:	SWOG 9108 (CALGB-9011, NCIC-CTGCL.1) A Phase III comparison of fludarabine phosphate vs chlorambucil vs (fludarabine) phosphate plus chlorambucil in previously untreated B-cell chronic lymphocytic leukemia				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	Mark R. Keaton, MAJ, MC		Facility:	Eisenhower Army Medical Center	
Department/Service:	Medicine/Oncology, Pathology		Associate Investigators:	Richard S. Foulke, MAJ, MC Jayanti K. Sen, COL, MC Don Shaffer, MAJ, MC Robert Krywicki, MAJ, MC	
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:	Feb 92 Continue	

Study Objective: 1) To compare in previously untreated CLL patients the response rates and progression free survival with the following three therapeutic regimens: i) fludarabine phosphate, ii) chlorambucil and iii) fludarabine phosphate + chlorambucil. 2) To determine whether the quality of life (need for transfusions, incidence of infections, and performance status) is superior using any of the three regimens. 3) To determine whether these two drugs (fludarabine phosphate and chlorambucil) are non-cross-resistant by a crossover design for patients failing to respond to the single agent to which they are initially randomized.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Subjects enrolled to date: 1

Progress: One patient enrolled.

DETAIL SUMMARY SHEET

Date:	20 Oct 92	Protocol #:	92-8	Status:	Completed
Title:	SWOG 9127 Evaluation of cisplatin, carboplatin and etoposide in selected Stage IIIb and Stage IV non-small cell lung carcinoma, Phase II				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	Mark R. Keaton, MAJ, MC		Facility: Eisenhower Army Medical Center		
Department/Service:	Medicine/Oncology, Pathology		Associate Investigators: Richard S. Foulke, MAJ, MC Paulino O. Vasallo, LTC, MC		
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results: Feb 92 Continue		

Study Objective: 1) To assess the survival of patients with non-small cell carcinoma of the lung treated with cisplatin, carboplatin and etoposide in an every four week schedule. 2) To assess the response rate of this combination in these patients. 3) To investigate the qualitative and quantitative toxicities of this drug combination administered in a Phase II study.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Subjects enrolled to date: 1

Progress: Accrual goal met, study closed by SWOG.

DETAIL SUMMARY SHEET

Date:	20 Oct 92	Protocol #:	92-36	Status:	Completed
Title:	SWOG 8991 A Phase II! Study of cisplatin plus etoposide combined with standard fractionation thoracic radiotherapy vs cisplatin plus etoposide combined with multiple daily fractionated thoracic radiotherapy for limited stage small cell lung cancer				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	Mark R. Keaton, MAJ, MC		Facility:	Eisenhower Army Medical Center	
Department/Service:	Medicine/Oncology, Pathology		Associate Investigators:	Richard S. Foulke, MAJ, MC Don Shaffer, MAJ, MC Jayanti K. Sen, COL, MC Robert Krywicki, MAJ, MC	
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective: To compare the median and long-term (i.e., > 2 year) survivals of limited stage SCLC patients receiving cisplatin/etoposide induction chemotherapy combined with concurrent thoracic radiotherapy given in either a standard, once daily fractionation scheme or a twice daily fractionation scheme. To compare intrathoracic within radiation portal and distant failure rates of these regimens. To compare the toxicities of standard fraction, concurrent thoracic radiotherapy with the toxicities of small, multiple daily fraction concurrent thoracic radiotherapy. To determine the clinical significance of variant morphology small cell carcinoma of the lung.

Technical Approach: Therapy will follow schema outlined in SWOG protocol

Subjects enrolled to date: 0

Progress: Accrual goal met, study closed by SWOG.

DETAIL SUMMARY SHEET

Date:	14 Oct 92	Protocol #:	92-37	Status:	Ongoing
Title:	SWOG 9007 Cytogenic studies in leukemia patients, ancillary				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):			Facility:		
Mark R. Keaton, MAJ, MC			Eisenhower Army Medical Center		
Department/Service:			Associate Investigators:		
Medicine/Oncology, Pathology			Richard S. Foulke, MAJ, MC		
Key Words:			Don Shaffer, MAJ, MC		
			Jayanti K. Sen, COL, MC		
			Robert Sywicki, MAJ, MC		
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective: To estimate the frequencies and prognostic significance of cytogenetic abnormalities in marrow or blood cells of leukemia patients prior to treatment on Southwest Oncology Group protocols and at various times in the course of their treatment. To estimate correlations between the presence of cytogenetic features and of clinical, pathophysiological, cellular, or molecular characteristics in these patients. To provide quality control for all Southwest Oncology Group cytogenetic data.

Technical Approach: Therapy will follow schema outlined in SWOG protocol

Subjects enrolled to date: 0

Progress: None.

DETAIL SUMMARY SHEET

Date:	14 Oct 92	Protocol #:	92-38	Status:	Ongoing
Title:	SWOG 9031 A Double-blind placebo controlled trial of daunomycin and cytosine arabinoside with or without rhG-CSF in elderly patients with acute myeloid leukemia, Phase III				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	Mark R. Keaton, MAJ, MC		Facility:	Eisenhower Army Medical Center	
Department/Service:	Medicine/Oncology, Pathology		Associate Investigators:	Richard S. Foulke, MAJ, MC Don Shaffer, MAJ, MC Jayanti K. Sen, COL, MC Robert Sywicki, MAJ, MC	
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective: To compare the complete response rates and durations of survival in patients aged 65 or older with acute myeloid leukemia (AML) when treated with standard doses of cytosine arabinoside (Ara-C) and daunorubicin (DNR), with or without recombinant human granulocyte-colony stimulating factor (rhG-CSF). To assess the frequency and severity of toxicities of the two treatment regimens. To compare the duration of neutropenia and thrombocytopenia; the total number of febrile days; the number of days of antibiotic therapy; the number and type of infection episodes; and the number of hospital days in patients treated with or without recombinant human granulocyte-colony stimulating factor (rhG-CSF). To correlate biological parameters including cell surface immunophenotype, ploidy and cytogenetics with clinical response.

Technical Approach: Therapy will follow schema outlined in SWOG protocol

Subjects enrolled to date: 0

Progress: None.

DETAIL SUMMARY SHEET

Date:	14 Oct 92	Protocol #:	92-39	Status:	Ongoing
Title:	SWOG 9139 Adjuvant therapy of primary osteogenic sarcoma, Phase II				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	Mark R. Keaton, MAJ, MC		Facility:	Eisenhower Army Medical Center	
Department/Service:	Medicine/Oncology, Pathology		Associate Investigators:	Richard S. Foulke, MAJ, MC Don Shaffer, MAJ, MC Jayanti K. Sen, COL, MC Robert Sywicki, MAJ, MC	
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective: To estimate the time to treatment failure and survival rate of the three drug combination adriamycin, cisplatin, and ifosfamide as adjunctive treatment of osteosarcoma of the extremity. To evaluate histopathologic tumor necrosis following preoperative adriamycin, cisplatin, and ifosfamide. To assess the feasibility of determining histopathologic tumor necrosis in a cooperative e group setting. To assess the influence of clinical prognostic variables on disease outcome. To assess the toxicity of this regimen.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Subjects enrolled to date: 0

Progress: None.

DETAIL SUMMARY SHEET

Date:	14 Oct 92	Protocol #:	92-40	Status:	Ongoing
Title:	SWOG 9151 Evaluation of topotecan in hepatoma				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	Mark R. Keaton, MAJ, MC		Facility:	Eisenhower Army Medical Center	
Department/Service:	Medicine/Oncology, Pathology		Associate Investigators:	Richard S. Foulke, MAJ, MC Don Shaffer, MAJ, MC Jayanti K. Sen, COL, MC Robert Sywicki, MAJ, MC	
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective: To evaluate the response rate of topotecan. To evaluate the qualitative and quantitative toxicities of topotecan administered in a Phase II study.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Subjects enrolled to date: 0

Progress: None.

DETAIL SUMMARY SHEET

Date:	14 Oct 92	Protocol #:	92-48	Status:	Ongoing
Title:	SWOG 9054 Ancillary bone mineral density study in premenopausal women on EST 5188 (Intergroup 0101)				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):			Facility:		
Mark R. Keaton, MAJ, MC			Eisenhower Army Medical Center		
Department/Service:			Associate Investigators:		
Medicine/Oncology, Pathology			Richard S. Foulke, MAJ, MC		
Key Words:			Don Shaffer, MAJ, MC		
			Jayanti K. Sen, COL, MC		
			Robert Sywicki, MAJ, MC		
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective: To determine whether tamoxifen (10 mg BID) protects against loss of bone mineral density in the lumbar spine and in the femur in premenopausal women with breast cancer following their being made postmenopausal by cytotoxic and ovarian function-suppressing hormonal therapy. To determine the effects Zoladex therapy has on bone mineral density in the lumbar spine and femur in premenopausal women with breast cancer following treatment with 6 cycles of cytotoxic chemotherapy. To determine the rates, pattern of rates and pattern of bone loss in the lumbar spine and femur occurring in premenopausal women treated with a standard course of 6 cycles of cytotoxic chemotherapy. To investigate the serum marker of bone mineral metabolism, serum osteocalcin, in a population of women undergoing significant changes in their bone density.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Subjects enrolled to date: 0

Progress: None.

DETAIL SUMMARY SHEET

Date:	14 Oct 92	Protocol #:	92-49	Status:	Ongoing
Title:	SWOG 9019 A Phase III. Randomized prospective comparison between chemotherapy plus radiotherapy and the same chemotherapy plus radiotherapy together with surgery for selected Stage IIIA (positive mediastinal nodes) and selected Stage IIIB (no malignant effusion) non-small cell lung cancer				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	Mark R. Keaton, MAJ, MC		Facility:	Eisenhower Army Medical Center	
Department/Service:	Medicine/Oncology, Pathology		Associate Investigators:	Richard S. Foulke, MAJ, MC Don Shaffer, MAJ, MC Robert D. Ranlett, LTC, MC Robert Sywicki, MAJ, MC	
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective: To assess whether concurrent chemotherapy and radiotherapy followed by surgical resection results in a significant improvement in progression-free, overall, and long-term survival compared to the same chemotherapy plus standard radiotherapy alone for patients with stage IIIa (Ne-positive) and selected IIIb non-small cell lung cancer. To evaluate the patterns of local and distant failure for patients enrolled in each arm of the study, in order to assess the impact of the therapy on local control and distant metastases.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Subjects enrolled to date: 0

Progress: None.

DETAIL SUMMARY SHEET

Date:	14 Oct 92	Protocol #:	92-50	Status:	Ongoing
Title:	SWOG 9035 Randomized trial of adjuvant immunotherapy with an allogenic melanoma vaccine for patients with intermediate thickness node negative malignant melanoma (T 3NOMO)				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	Mark R. Keaton, MAJ, MC		Facility:	Eisenhower Army Medical Center	
Department/Service:	Medicine/Oncology, Pathology		Associate Investigators:	Richard S. Foulke, MAJ, MC Don Shaffer, MAJ, MC, Paulino D. Vasallo, COL, MC Robert Sywicki, MAJ, MC	
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective: To compare disease-free survival and overall survival between patients with T3NOMO malignant melanoma who receive adjuvant immunotherapy with an allogeneic melanoma vaccine versus no adjuvant treatment. To evaluate the toxicity of adjuvant immunotherapy with an allogeneic melanoma vaccine in patients with T3NOMO malignant melanoma.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Subjects enrolled to date: 0

Progress: None.

DETAIL SUMMARY SHEET

Date:	14 Oct 92	Protocol #:	92-51	Status:	Ongoing
Title:	SWOG 9116 Evaluation of piroxantrone in disseminated malignant melanoma, Phase II				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	Mark R. Keaton, MAJ, MC		Facility:	Eisenhower Army Medical Center	
Department/Service:	Medicine/Oncology, Pathology		Associate Investigators:	Richard S. Foulke, MAJ, MC Don W. Shaffer, MAJ, MC Paulino D. Vasallo, COL, MC Robert Sywicki, MAJ, MC	
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective: To evaluate the response rate of disseminated malignant melanoma treated with piroxantrone. To assess the qualitative and quantitative toxicities of piroxantrone administered in a Phase II study.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Subjects enrolled to date: 0

Progress: None.

DETAIL SUMMARY SHEET

Date:	20 Oct 92	Protocol #:	92-62	Status:	Ongoing
Title:	SWOG 9062 - Evaluation of 96 hour infusion 5-FU + cisplatin + alpha interferon in patients with recurrent/metastatic squamous cell carcinoma of head and neck, Phase II				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	Mark R. Keaton, MAJ, MC		Facility:	Eisenhower Army Medical Center	
Department/Service:	Medicine/Oncology, Pathology		Associate Investigators:	Richard S. Foulke, MAJ, MC Don Shaffer, MAJ, MC Robert Krywicki, MAJ, MC Jayanti K. Sen, COL, MC	
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective: To evaluate the complete response rate i order to assess whether this regimen should be advanced to further studies. To evaluate the qualitative and quantitative toxicities associated with this regimen. To assess the feasibility of this regimen.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled during reporting period: 0

Progress: None to date.

DETAIL SUMMARY SHEET

Date:	20 Oct 92	Protocol #:	92-63	Status:	Ongoing
Title:	SWOG 9134 - A Phase II, trial of taxol and granulocyte-colony stimulating factor (G-CSF) in patients with advanced soft-tissue sarcoma				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	Mark R. Keaton, MAJ, MC		Facility:	Eisenhower Army Medical Center	
Department/Service:	Medicine/Oncology, Pathology		Associate Investigators:	Richard S. Foulke, MAJ, MC Don Shaffer, MAJ, MC Robert Krywicki, MAJ, MC Jayanti K. Sen, COL, MC	
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective: To evaluate the clinical rate of taxol administered with G-CSF in advanced soft tissue sarcomas. To define the qualitative and quantitative toxicities of taxol administered with G-CSF in a Phase II study.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled during reporting period: 0

Progress: None to date.

DETAIL SUMMARY SHEET

Date:	20 Oct 92	Protocol #:	92-64	Status:	Ongoing
Title:	SWOG 9135 - A Phase II trial of taxol and granulocyte-colony stimulating factor (G-CSF) in patients with pancreatic adenocarcinoma				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	Mark R. Keaton, MAJ, MC		Facility:	Eisenhower Army Medical Center	
Department/Service:	Medicine/Oncology, Pathology		Associate Investigators:	Richard S. Foulke, MAJ, MC Don Shaffer, MAJ, MC Robert Krywicki, MAJ, MC Jayanti K. Sen, COL, MC	
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective: To evaluate the clinical response rate of taxol administered with G-CSF in pancreatic adenocarcinoma. To define the qualitative and quantitative toxicities of taxol administered with G-CSF in this patient population.

Technical Approach: Therapy will follow schema outlined in SWOG protocol

Number of subjects enrolled to date: 0

Progress: None to date.

DETAIL SUMMARY SHEET

Date:	20 Oct 92	Protocol #:	92-65	Status:	Ongoing
Title:	SWOG 9147 - Evaluation of tamoxifen in desmoid tumors, Phase II				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	Mark R. Keaton, MAJ, MC		Facility:	Eisenhower Army Medical Center	
Department/Service:	Medicine/Oncology, Pathology		Associate Investigators:	Richard S. Foulke, MAJ, MC Don Shaffer, MAJ, MC Robert Krywicki, MAJ, MC Jayanti K. Sen, COL, MC	
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective: To assess the response rate of fibromatosis to treatment with tamoxifen. To assess the clonality in "informative" female patients (i.e., females heterozygous for the genetic locus) utilizing a molecular probe for an X-linked enzyme.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled to date: 0

Progress: None to date.

DETAIL SUMMARY SHEET

Date:	8 Oct 92	Protocol #:	92-68	Status:	Ongoing
Title:	SWOG 8955 - Treatment of Stage D, Hormone Refractory Carcinoma of the Prostate with 5-Fluorouracil and Roferon-A, Phase II				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	Mark R. Keaton, MD, MAJ, MC		Facility:	Eisenhower Army Medical Center	
Department/Service:	Medicine/Oncology		Associate Investigators:	Richard S. Foulke, MD, MAJ, MC Jayanti K. Sen, MD, COL, MC	
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective: To evaluate the likelihood of response of hormone refractory, metastatic carcinoma of the prostate treated with F-FU and Roferon-A in order to assess whether this regimen should be advanced to further studies. To assess the qualitative and quantitative toxicities of this regimen administered in a phase II study.

Technical Approach: Therapy will follow schema outlined in SWOG protocol

Number of subjects enrolled to date:

Progress: None to date.

DETAIL SUMMARY SHEET

Date:	8 Oct 92	Protocol #:	92-69	Status:	Ongoing
Title:	SWOG 9059 - Phase III Comparison of Standard Radiotherapy <i>versus</i> Radiotherapy Plus Simultaneous Cisplatin, <i>versus</i> Split-Course Radiotherapy Plus Simultaneous Cisplatin and 5-Fluorouracil, in Patients with Unresectable Squamous Cell Carcinoma of the Head and Neck				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	Mark R. Keaton, MD, MAJ, MC		Facility:	Eisenhower Army Medical Center	
Department/Service:	Medicine/Oncology		Associate Investigators:	Richard S. Foulke, MD, MAJ, MC Jayanti K. Sen, MD, COL, MC	
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective: To compare the effectiveness of standard radiation therapy alone to radiation therapy and simultaneous chemotherapy with cisplatin to split-course radiation therapy with cisplatin and 5-fluorouracil infusion in patients with unresectable Stage III and IV squamous cell carcinoma of the head and neck. Endpoints will include complete response rate, time to treatment failure, and overall survival. To compare the relative toxicities of these three treatment arms in this patient population. To compare patterns of relapse or treatment failure among these regimens. To further assess the role, timing, and success of surgery in patients achieving a response to non-operative therapy.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled to date:

Progress: None.

DETAIL SUMMARY SHEET

Date:	8 Oct 92	Protocol #:	92-70	Status:	Ongoing
Title:	SWOG 9129, Phase III Randomized Study of All-Trans Retinoic Acid <i>versus</i> Cytosine Arabinoside and Daunorubicin as Induction Therapy for Patients with Previously Untreated Acute Promyelocytic Leukemia				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	Mark R. Keaton, MD, MAJ, MC		Facility:	Eisenhower Army Medical Center	
Department/Service:	Medicine/Oncology		Associate Investigators:	Richard S. Foulke, MD, MAJ, MC Jayanti K. Sen, MD, COL, MC	
Key Words					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective: To compare the complete remission rate and disease-free survival of TRA to that achieved with conventional induction chemotherapy including Cytosine Arabinoside plus Daunorubicin in Patients with previously untreated APL. To compare the toxicities of TRA to those of Cytosine Arabinoside plus Daunorubicin as induction therapy in APL. To determine the value of maintenance therapy with TRA.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled to date:

Progress: None.

DETAIL SUMMARY SHEET

Date:	8 Oct 92	Protocol #:	92-71	Status:	Ongoing
Title:	SWOG 9150 - Evaluation of Topotecan in Gastric Cancer, Phase II				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	Mark R. Keaton, MD, MAJ, MC		Facility:	Eisenhower Army Medical Center	
Department/Service:	Medicine/Oncology		Associate Investigators:	Richard S. Foulke, MD, MAJ, MC Jayanti K. Sen, MD, COL, MC	
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective: To evaluate the response rate of gastric carcinoma treated with topotecan. To evaluate the qualitative and quantitative toxicities of topotecan administered in a Phase II study.

Technical Approach: Therapy will follow schema outlined in SWOG protocol

Number of subjects enrolled to date:

Progress: None

DETAIL SUMMARY SHEET

Date:	21 Oct 92	Protocol #:	78-14	Status:	Terminate
Title:	Intraocular Lens Study				
Start Date:	Nov 80	Est. Compl. Date:			
Principal Investigator(s):	Robert A. Mazzoli, MAJ, MC		Facility:	USA MEDDAC, Ft Benning, GA	
Department/Service:	Surgery/Ophthalmology		Associate Investigators:	Elizabeth A. Hansen, MAJ, MC Steven L. Henslee, MD	
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective: Provide data to support FDA approval for marketing intraocular devices.

Technical Approach: Surgical insertion of intraocular lens. Presently, intraocular lenses selected for implantation include IOLAD Model G108B, 3M Vision Care Style 83, Precision-Cosmet Model 8201, and Cilco Styles SK21VO, SAC5VO.

Number of subjects enrolled to date: 679

Progress: No response from PI, terminate.

DETAIL SUMMARY SHEET

Date:	6 Oct 92	Protocol #:	78-14	Status:	Ongoing
Title:	Intraocular Lens Study				
Start Date:	Oct 81	Est. Compl. Date:			
Principal Investigator(s): Emil A. Stein, CPT, MC		Facility: USA MEDDAC, Ft Campbell, KY			
Department/Service: Surgery/Ophthalmology		Associate Investigators:			
Key Words:					
Accumulative MEDCASE Cost:		Periodic Review Results:			

Study Objective: To provide to cataract patients the latest development in ophthalmic surgery concerning the correction of surgical aphakia.

Technical Approach: Extracapsular cataract extraction followed by the implantation of an intraocular lens implant.

Subjects enrolled to date: 333

Subjects enrolled for the reporting period: 96

Progress: Continued excellent surgical and visual results without significant complications.

DETAIL SUMMARY SHEET

Date:	6 Oct 92	Protocol #:	78-14A	Status:	Ongoing
Title:	Pediatric Intraocular Lens Study				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	Emil A. Stein, MAJ, MC		Facility:	USA MEDDAC, Ft Campbell, KY	
Department/Service:	Surgery/Ophthalmology		Associate Investigators:		
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective: To provide pediatric patients with the latest development in ophthalmic surgery for the treatment of surgical aphakia.

Technical Approach Extracapsular cataract extraction followed by implantation of an intraocular lens implant.

Subjects enrolled to date: 2

Subjects enrolled for reporting period: 1

Progress: Excellent surgical results without significant complications.

DETAIL SUMMARY SHEET

Date:	21 Oct 92	Protocol #:	91-58	Status:	Completed
Title:	Physical and psychosocial impact on activation on Army Reserve Nurses				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):			Facility:		
Nancy M. Ryan, MAJ, AN			USA MEDDAC, Ft Campbell, KY		
Department/Service:			Associate Investigators:		
Nursing			Catherine B. Talley, LTC, AN		
Key Words:			Stephen N. Xenakis, COL, MC		
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective: To systemically examine, as it is experienced, the physical and psychosocial impact of activation on Army reserve nurses.

Technical Approach: The study requires periodic completion of questionnaires which measure physical and psychosocial variables. The PI is responsible for all aspects of this study. Assistance with the mechanics of data collection is obtained from fellow Army Nurse Corps officers as needed. This project has no specific funding source. Postage for mailed surveys was paid by Blanchfield Army Community Hospital, Ft Campbell, KY. Other costs for the project (duplication of forms, computer time, etc.) have been absorbed by the Ohio State University College of Nursing, where the PI is employed.

Subjects enrolled to date: 81

Progress: Reserve mobilization training focuses on specialty skills and soldiers' common tasks, but does not prepare individuals for the physical and psychological realities of activation. The purpose of this descriptive, multiphasic research was to systematically examine, as it was experienced, the impact of activation and subsequent de-activation on 81 Army reserve nurses. The variables measured included somatic symptoms, psychosocial effects, stressors, coping strategies and positive aspects of the experience. Some nurses experienced physical and psychosocial symptoms consistent with Post Traumatic Stress Disorder. Lessons learned from this study will help Army Reserve units to be more pro-active in mobilization preparation and training.

DETAIL SUMMARY SHEET

Date:	5 Nov 92	Protocol #:	92-17	Status:	Terminated
Title:	Effects of rest and exercise on patellofemoral pain syndrome in active duty patients				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	CPT Jan W. Durst, SP		Facility:	USA, MEDDAC, Ft Campbell, KY	
Department/Service:	Surgery/Physical Therapy		Associate Investigators:	MAJ Billie J. Randolph, SP 1LT Edgar Torres, SP Greer A. Busbee, MD 1LT Craig D. Allen, SP	
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Objective: To determine the effectiveness of rest and a specific exercise program for the treatment of PFS in young male active duty soldiers.

Technical Approach:

Subjects enrolled to date: 12

Progress: Terminated due to lack of personnel to conduct study.

DETAIL SUMMARY SHEET

Date:	6 Nov 92	Protocol #:	92-33	Status:	Ongoing
Title:	Prolotherapy in the treatment of chronic low back pain - A double-blind study				
Start Date:			Est. Compl. Date:		
Principal Investigator(s): Michael D. Jacobson, MAJ, MC Mark A. Bonneville, MAJ, MC			Facility: USA MEDDAC, Ft Campbell, KY		
Department/Service: Family Practice			Associate Investigators: Walter E. Carnahan, CPT, MC		
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Objective: To demonstrate the effectiveness of using a proliferant solution for the treatment of chronic, mechanical low back pain.

Technical approach:

Progress: Study is ongoing.

DETAIL SUMMARY SHEET

Date:	6 Oct 92	Protocol #:	92-55	Status:	Ongoing
Title:	The effects of parental deployment on childhood behavior				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	Marvin C. Arnold, MAJ, MS		Facility:	USA MEDDAC, Ft Campbell, KY	
Department/Service:	Psychiatry		Associate Investigators:	Stephen N. Xenakis, COL, MC	
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective: To determine those elements that impact on family functioning during deployment of the soldier, particularly on the children. To determine what neuro-psychological, social, and behavioral dysfunction occurred in children of deployed parents before, during and after Operation Desert Storm.

Technical Approach: (1) **Experimental design:** The study utilizes a stratified multi-cell (five cells) design. The population consists of parents of children in the following categories: single parents, dual career couples, intact/traditional families, parents of disturbed children (seen at Child Psychiatry, Community Mental Health Activity and Social Work Services during deployment), parents of nondisturbed children (seen at regular Family Practice visits). Stratified probability sampling will be employed to select the research sample. Sample size estimation is 200 subjects per cell. Sample size determination was made by selecting a population size (n) that is sufficient for the standard error of estimate not to exceed 0.05.

(2) **Manpower:** Consists of the Principal Investigator, a 91G Behavioral Science Specialist, and five research assistants employed at Blanchfield Army Hospital.

(3) **Funding:** Obtained from the Department of Military Psychiatry, Walter Reed Army Institute of Research, Washington, DC. Funding required for FY 92 only.

(4) **Number of subjects enrolled to date:** 1,500

(5) **Number of subjects enrolled for reporting period:** 1,500

(6) **Nature and extent of significant adverse reactions:** No adverse reactions to date. All subjects required to read and sign the Volunteer Agreement Affidavit.

Progress: Data collection is continuing at Blanchfield Army Hospital until 30 Sep 92. As of this date no conclusions have been made regarding the research. No studies have been terminated or completed. There have been no presentations at scientific meetings nor submission of articles for

publication related to this research.

DETAIL SUMMARY SHEET

Date:	21 Oct 92	Protocol #:	91-83	Status:	completed
Title:	Comparison of tympanic thermometry to rectal thermometry in an ambulatory pediatric clinic				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):	Shashi A.M. Kumar, M.D.		Facility:	USA MEDDAC, Redstone Arsenal, AL	
Department/Service:	Pediatrics		Associate Investigators:	Pamela Thorson, RN	
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective: To evaluate the accuracy and precision of tympanic temperature in children less than three years old using ear tug maneuver and comparing it to simultaneously obtained rectal temperature.

Technical Approach: The two techniques will be compared for accuracy.

Subjects enrolled to date:

Progress: Study completed.

DETAIL SUMMARY SHEET

Date:	6 Oct 92	Protocol #:	90-38	Status:	Completed
Title:	Comparison of cefpodoxime proxetil and ciprofloxacin in the treatment of acute pneumonia in geriatric patients				
Start Date:	Jun 91	Est. Compl. Date:			
Principal Investigator(s): John A. Powell, MAJ, MC		Facility: USA MEDDAC, Ft Rucker, AL			
Department/Service: Medicine		Associate Investigators: Jeff Stone, MAJ, MC Paul Hunn, CPT, MC Roland J. Weisser, Jr., COL, MC			
Key Words:					
Accumulative MEDCASE Cost:		Periodic Review Results:			

Study Objective: To compare the efficacy and safety of orally administered cefpodoxime proxetil and ciprofloxacin in the treatment of acute pneumonia caused by pathogens susceptible to these two antimicrobials, in geriatric patients.

Technical Approach: This is a randomized, comparative, observer-blinded, parallel-treatment, multicenter study evaluating efficacy and safety of cefpodoxime proxetil in acute pneumonia. Patients will be selected based on signs and symptoms of pneumonia caused by organisms expected to be susceptible to cefpodoxime proxetil and ciprofloxacin.

Subjects enrolled to date: 3

Subjects enrolled for the reporting period: 0

Progress: Study completed.

DETAIL SUMMARY SHEET

Date:	6 Oct 92	Protocol #:	91-65	Status:	Completed
Title:	Comparison of cefpodoxime proxetil and cefaclor in the treatment of acute exacerbation of chronic obstructive pulmonary disease in adult patients				
Start Date:	Sep 91	Est. Compl. Date:			
Principal Investigator(s):	John A. Powell, MAJ, MC		Facility:	USA MEDDAC, Ft Rucker, AL	
Department/Service:	Medicine		Associate Investigators:	Paul Hunn, CPT, MC	
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective: This study compares the efficacy of orally administered cefpodoxime proxetil and cefaclor in the treatment of bronchitis caused by susceptible pathogens, in patients with exacerbation of COPD. The relative clinical efficacy of the administered drugs will be measured by clinical response. The microbiologic efficacy will be assessed by pretreatment and followup cultures. This study will evaluate and compare the safety and tolerance of both drugs.

Technical Approach: Randomized study, double blinded evaluating efficacy of cefpodoxime proxetil in treatment of exacerbation of COPD in that population.

Subjects enrolled to date:

Subjects enrolled for the reporting period:

Progress: Study completed.

DETAIL SUMMARY SHEET

Date:	21 Oct 92	Protocol #:	92-66	Status:	Completed
Title:	The relationship of self-care agency and achievement of mastery in childbirth				
Start Date:			Est. Compl. Date:		
Principal Investigator(s):			Facility:		
	Lori Campbell, RN			USA MEDDAC, Ft Stewart, GA	
Department/Service:			Associate Investigators:		
	OB-GYN				
Key Words:					
Accumulative MEDCASE Cost:			Periodic Review Results:		

Study Objective: To assess the use of self-care in relationship to those who attend childbirth education classes.

Technical Approach: Utilize the exercise of self-care agency before and after childbirth education. Due to time constraints and minimal participation, subjects were not followed after delivery.

Number of subjects enrolled to date: 52

Progress: Utilizing ANOVA and a paired T-test the data collected in the study did not support the hypotheses that self-care agency would increase after childbirth education classes.

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